



**COLORADO**  
Department of Public  
Health & Environment

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To: Members of the State Board of Health

From: James Jarvis, Health Physicist, Hazardous Materials and Waste Management Division

Through: Gary Baughman, Division Director *GB*

Date: February 2, 2015

Subject: **Rulemaking Hearing**  
Proposed Amendments to 6 CCR 1007-1, Part 12, "Fees for Radiation Control Services" and 6 CCR 1007-1, Part 2, "Registration of Radiation Machines, Facilities, and Services", for the rulemaking hearing to occur on February 18, 2015

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The Division is proposing changes to the fees it charges for services which are outlined in Part 12 of the regulations, titled *Fees for Radiation Control Services*. Changes are also proposed for Part 2 of the regulations, titled Registration of Radiation Machines, Facilities, and Services, necessary to support the proposed changes to Part 12.

The proposed regulatory changes are being initiated to address a projected budget shortfall in program funding. During a recent analysis of fees, budgets and expenditures, it was determined that the program will have a projected income shortfall of approximately \$394K for FY 2015. Fees for radioactive materials licensing have not changed since 2009 and fees for radiation machine services have not changed since 2001. The Division is proposing fee increases (above the current fees) ranging from 16%-25% which will impact approximately 975 specific and general radioactive materials licensees and all radiation machine registrants. Additionally, the Division is proposing a new radiation machine facility registration fee of \$50 per year per facility to meet department costs for administering radiation control services to support the approximate 5,200 facilities using radiation machines in Colorado.

The proposed amendment to Part 2 adds language consistent with the proposed changes in Part 12. Language is added to reference the proposed facility registration fee for radiation control services, and to indicate that Service Company, Qualified Inspector, and Qualified Expert registrations are for a 1-year period. Additionally, two typographical errors are corrected in the proposed amendment.

Over 6,000 stakeholders were notified of the proposed changes and the opportunity to ask questions and comment via email, and were offered the opportunity to participate in three stakeholder meetings. The Division received written comments from ~20 individuals as well as a few comments from the 12 individuals participating in the three stakeholder meetings. The primary concern expressed by radiation machine facility stakeholders were that the increase in radiation machine fees, and in particular, the proposed annual \$50 registration application fee would have a negative impact on small businesses in the medical field (primarily dentistry, veterinary, and chiropractic medicine). Additionally, stakeholders commented on the need for government entities to work within established budgets. One radioactive materials licensee provided comments supporting the proposed changes while the remainder of comments generally opposed the proposed fees.

Further details on the proposed changes are listed in a Statement of Basis and Purpose and Specific Statutory Authority for the proposed revised rule, which, along with a Regulatory Analysis and supporting information, is available at:  
<http://www.colorado.gov/pacific/cdphe/radregs>

cc: Deborah Nelson, Administrator, State Board of Health

STATEMENT OF BASIS AND PURPOSE  
AND SPECIFIC STATUTORY AUTHORITY  
for Amendments to  
**6 CCR 1007-1, Radiation Control, Part 12, Fees for Radiation Control Services and  
Part 2, Registration of Radiation Machines, Facilities, and Services**

**Basis and Purpose.**

The Colorado Radiation Control Act, Title 25, Article 11, Colorado Revised Statutes (the Act), requires the State Board of Health to formulate, adopt and promulgate rules and regulations pertaining to radiation control.

Section 25-11-103 of the Act requires the Colorado Department of Public Health and Environment (Department) to develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing radiation, including requiring registration of sources of ionizing radiation such as radiation machines and to issue licenses governing the use of radioactive materials.

Section 25-11-104 of the Act requires Colorado's radiation regulations to be modeled after the Suggested State Regulations for Control of Radiation (SSRCR) of the Conference of Radiation Control Program Directors, Inc., except when the Board of Health concludes, on the basis of detailed findings, that a substantial deviation from the SSRCR is warranted. The Department's regulations, in certain parts, must also be compatible with the regulations adopted by the U.S. Nuclear Regulatory Commission (NRC). The Act establishes the SSRCR as the model for Colorado to use in adopting NRC regulatory provisions. In some instances, maintaining consistency with the SSRCR may not be possible due to the model regulation being out of date with NRC changes or where no model regulation exists.

Section 25-11-104(6) of the Radiation Control Act requires:

- The state board of health shall formulate, adopt, and promulgate a fee schedule for radiation control services provided by the Department;
- The board of health shall provide for sufficient revenues from fees to reimburse the state for cost of the radiation control services;
- The fees shall be related to the actual costs incurred in administering such radiation control services; and
- Licenses and fees shall be in accordance with policies and priorities of NRC.

Due to the differing funding sources and fee structure variances in radiation programs from state to state, there is no established SSRCR which is equivalent to Colorado Part 12. The SSRCR equivalent to Colorado Part 2, (known as SSRCR Part "B") is generic in nature thus permitting individual states to shape the rule to fit the individual registration and business processes of the state. The NRC does not require Agreement States to collect fees as a matter of compatibility. However, the NRC does require that a radiation control program have a stable source of funding. The Colorado Radiation Control Program (Program) in the Hazardous Materials and Waste Management Division (Division) is sustained almost wholly from the radiation control cash fund (Fund) derived from the fees charged. Without sufficient funding support, the State of Colorado would not have an adequate radiation control program. The consequence of such a finding by NRC could be that NRC would reassert its authority over Colorado licensees, imposing NRC's higher fees on Colorado licenses. Under such a scenario radioactive materials licensees would also be required to work with a federal regulatory agency not physically located in Colorado. The proposed amendments to Part 12 and Part 2

are written to follow statutory requirements and Colorado's specific business processes and program which are unique and specific to Colorado.

The Department is proposing revisions to Part 12, *Fees for Radiation Control Services*, of the *State of Colorado Rules and Regulations Pertaining to Radiation Control*. The most recent changes to Part 12 were adopted March 16, 2011 and became effective April 30, 2011. The 2011 changes did not involve adjustments to fees. The currently proposed amendment is intended to adequately provide for the Program's costs for radiation control services through fiscal year 2017, at which time fees and costs will be reviewed again. The adjustments maintain the equitable distribution of program costs among existing licensees and radiation machine registrants.

Concurrent with the Part 12 changes, the Program is also proposing minor changes to Part 2, *Registration of Radiation Machines, Facilities, and Services*, necessary to clarify and support the changes to Part 12. Part 2 was previously adopted June 18, 2014 and became effective August 14, 2014. The proposed Part 2 change includes added language to incorporate the annual radiation machine facility registration fee and to specify that the registrations for qualified inspectors, qualified experts and service companies are issued annually. An analysis of overall annual fees was conducted. In 2014 the Program evaluated projected costs and revenue under the current fee schedule. The analysis indicates that a deficit is now projected for the current fiscal year (FY 2014-15) and beyond if the fee schedule is not altered. The proposed approach provides the increased revenue needed for the department to administer radiation control services.

Each radioactive material licensee in Part 12, Appendix 12A has a fixed annual fee, fixed new application fee and fixed fee for a non-routine inspections. Some licensees are subject to full-cost-fee recovery at an hourly billable rate. No changes to the hourly rate are proposed in this rulemaking as the analysis has indicated that the current hourly rate is adequate to support such hourly based activities and is consistent with other hourly rates in the Division.

The Program proposes five types of fee adjustments in the Part 12 rule:

- (1) An increase of 20% in the radiation machine certification label fee from the current \$50 to \$60 per machine label;
- (2) The establishment of a new annual radiation machine facility registration fee for radiation control services of \$50;
- (3) An increase of 20% in the application review fee (from the current \$50 to \$60) for certain radiation machine operators (limited scope operators, bone densitometry operators, provisional mammographers);
- (4) An increase of 25% in the application review fee (from the current \$80 to \$100 annualized) for qualified experts, qualified inspectors, and service companies, and making the application cycle annual rather than the current biennial cycle; and
- (5) An increase of 16-20% in annual fees and non-routine inspection fees for specific and the annual fee for general radioactive materials licensees. (Fees vary by license category).

Part 12, Section 12.11 of the rule, authorizes the Department to adjust all fees and the cost per person-hour every six months based on the consumer price index (CPI). A consumer price index is not calculated for the whole State of Colorado. According to a table published on the Legislative Council web site, <http://www.colorado.gov/cs/Satellite/DOLA-Main/CBON/1251594680280>, the CPI, calculated semiannually for the Denver-Boulder-Greeley metropolitan statistical area, is often used as a proxy for the inflation rate of Colorado. Since 2001 when radiation machine fees were last adjusted, the CPI has increased approximately 27% (~2-2.5% per year on average). Since 2009, when the radioactive materials license fees were last adjusted, the CPI has increased by approximately 11% (~2.75% per year). To account for an additional CPI increase in 2014-15, an increase of 16% is proposed for radioactive materials fees.

The overall impact of the proposed modifications would be to increase total revenue by approximately \$394,319 for FY 2014-15. Overall, Colorado's proposed radioactive materials annual fees are comparable to surrounding states and on average about 45% of the equivalent NRC fees.

Note that editorial comments, notes, and information shown in the right side margin of the draft proposed rule are for information only to aid the reader, and are not considered part of the regulation. These will be removed from the final regulation prior to submission to the Colorado Secretary of State's office for publishing in the Colorado register.

**Specific Statutory Authority.**

These rules are promulgated pursuant to the following statutory provisions: 25-1.5-101(1)(k), 25-1.5(1)(l), 25-11-103, 25-11-104, and 25-1-108, C.R.S.

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SUPPLEMENTAL QUESTIONS

**Is this rulemaking due to a change in state statute?**

\_\_\_\_\_ Yes, the bill number is \_\_\_\_\_; rules are \_\_\_\_ authorized \_\_\_\_ required.  
\_\_\_X\_\_\_ No

**Is this rulemaking due to a federal statutory or regulatory change?**

\_\_\_\_\_ Yes  
\_\_\_X\_\_\_ No

**Does this rule incorporate materials by reference?**

\_\_\_\_\_ Yes  
\_\_\_X\_\_\_ No

**Does this rule create or modify fines or fees?**

\_\_\_X\_\_\_ Yes  
\_\_\_\_\_ No

## REGULATORY ANALYSIS

for Amendments to

### 6 CCR 1007-1, Radiation Control, Part 12, Fees for Radiation Control Services and Part 2, Registration of Radiation Machines, Facilities, and Services

1. A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

The Radiation Program is part of the Hazardous Materials and Waste Management Division at the Colorado Department of Public Health and Environment. The mission of the program is to protect the citizens of Colorado from the hazards of radiation by regulating radioactive materials and radiation machine use throughout the state. The program achieves its mission primarily by licensing and inspecting facilities that use radioactive materials and requiring and tracking inspections of radiation machines through (privatized) qualified inspectors. Radioactive materials and radiation machines are used in a wide range of fields including the healing arts (medicine, chiropractic, veterinary, dentistry, and podiatry), industry (construction, security, analytical, research, mining, and oil and gas) and higher education (research, teaching). Therefore, the entities that will be affected by the proposed rule change and proposed fee increases include any organization using radioactive materials requiring licensing or any organization using radiation producing machines requiring registration. These entities include large and small businesses, some governmental entities, and institutions of higher education all of whom are regulated by the Radiation Program due to their use of radioactive materials and/or radiation (X-Ray) machines. Currently, there are approximately 5,200 facilities registered to use radiation machines; approximately 319 specific radioactive materials licensees; approximately 418 general radioactive materials licensees; and an additional ~1000 other individuals and entities registered with the Department as operators, inspectors, or service providers for radiation machines.

The Radiation Program charges fees for its services including the licensing and inspection fees for persons using radioactive materials. Fees are charged and received for the registration of radiation machines (and facilities) through sale of radiation machine certification labels. Fees are also charged for the registration of the private individuals who perform inspections on radiation machines, for the companies who perform service and maintenance on radiation machines, and certain individuals who operate radiation machines. These registration requirements are in place to insure that only qualified individuals perform such activities. All of these entities will bear the cost of the proposed changes and fee increases. Similarly, the citizens of Colorado along with all of these entities will receive the benefit of the continued regulatory program and the proposed rule/fee, since the program helps to ensure the safe use of radioactive materials and the safe output (radiation levels), operation, and maintenance of radiation machines.

Part 2 is specific to radiation producing (x-ray) machines and therefore, only those entities registered with the program as a facility, qualified inspector, qualified expert, certain machine operators, or service companies would be specifically impacted by the Part 2 changes. The Part 2 changes are necessary to clarify and support the proposed Part 12 changes. Although Part 2 is only applicable to

radiation machine registrants, the Part 12 changes impact all radioactive materials licensees and radiation machine registrants.

2. To the extent practicable, the following is a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

The quantitative impact of the proposed rule changes in Parts 12 and 2 and associated fee change is that licensees and registrants will be required to pay higher fees for licensing and registration activities ranging from 16% to 25% above current fee amounts. Additionally, under the proposed Part 2 changes each x-ray machine facility will be required to register and pay a fee annually; and qualified inspectors, qualified experts, and service companies will be required to register with the department on an annual rather than biennial cycle. The table below outlines the changes in fees in term of percent increase by type of entity for the current fees and the approximate number of entities impacted.

Entity Type	% Increase in fees over current fee amount [Approximate number of entities impacted]
<b>-RADIATION MACHINE FEES-</b>	
Radiation (X-Ray) Machine Registration - Certification Label Fee Per Machine <sup>1</sup>	20% [5,200]
Qualified Inspector, Qualified Expert, Service Company Registration Fee <sup>2</sup>	25% [~354]
Application Review Fee - Provisional Mammography Operator	20% [30-34 per year]
Review of adequate training for Limited Scope Operators, Bone Densitometry Operators, CT Operators, Service Company Engineers	20% [450+ per year]
Radiation Machine enforcement action/inspection fee	18% [~10 per year] <sup>3</sup>
<b>-RADIOACTIVE MATERIALS LICENSEE FEES-</b>	
Radioactive Materials General Licensee Annual Registration - All (excluding in-vitro)	20% [~417]
Radioactive Materials General Licensee Annual Registration - in-vitro	20% [1]
Specific Licensee Annual Fee - All Categories (full fee, non-small entities)	16% [~255]
Specific Licensee Annual Fee - "Tier I" Small Entity	20% [~19]
Specific Licensee Annual Fee - "Tier II" Small Entity	16% [~45]
Radioactive materials non-routine inspection fee maximum amount. (Non-routine inspections are based the hourly rate for which no changes are proposed) <sup>4</sup>	16% [<~4 per year]

<sup>1</sup> Inspection/certification frequencies vary from 1-3 years and therefore not all machines will require an inspection certification label each year.

<sup>2</sup> The QI, QE, and Service Company registration fee is currently a biennial (every 2 year) fee. Under the proposed changes, this will become an annual fee.

<sup>3</sup> The number of enforcement actions/inspection fees is not fully predictable for future activities as it is dependent upon regulatory compliance by the regulated entity. Historically, for 2011-2013 the hourly fee for non-routine inspections/enforcement actions has been invoked ~10 times per year on average, with a typical non-routine inspection fee of less than \$300 per facility. This fee is in addition to any administrative penalty assessed in the event of significant non-compliance findings.

<sup>4</sup> Non-routine inspection fees for radioactive materials licensees are invoked infrequently and only in cases of escalated enforcement where a licensee must be re-inspected at a shorter than standard frequency. The range per year values shown is for 2010-2014. Routine inspection costs are included in the annual license fee. This fee is in addition to any administrative penalty assessed in the event of significant non-compliance findings.

In addition to the current fees charged as outlined in the table above, the Division is proposing a new nominal annual radiation machine facility registration fee of \$50 per year. This will impact all ~5,200 facilities registered to use radiation machines but who do not currently pay a registration fee.

3. The probable costs to the agency and to any other agency for the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

It is expected that some minimal additional effort by the Radiation Program will be necessary to implement the proposed annual facility registration fee identified in the proposed changes to Part 12 and Part 2, to include annual notifications/billing activities for the fee, payment tracking, and follow-up for those registrants failing to pay fees in a timely manner. These activities are expected to be carried out by the Radiation Program and a centralized business process unit within the Division. Efforts are being initiated to allow the registration form and fee to be completed/paid online, thus minimizing some agency costs, although there will be some up-front costs to establish the required business process. Additionally, the program will be implementing a new database program and electronic filing procedures that will further streamline the work required to register and track radiation machines and radiation machine facilities. This increased efficiency is anticipated to offset some of the additional work of collecting the annual facility registration fee and the annual renewal cycle for Qualified Inspectors, Qualified Experts and Service Companies.

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

The current X-ray certification registration program for the 14,500 radiation machines in Colorado is maintained by a staff of ~4.0 FTE, including program management. One additional program FTE equivalent is dedicated and funded separately (by the US Food and Drug Administration) for the annual inspection of mammography machines.

The benefits of the proposed rule changes and associated fee increases will allow the program to continue at its current workload. Efforts are currently underway to improve the programs efficiency through development of web based data handling and payment methods.

Inaction on raising fees may result in a loss of staff (Full Time Equivalent or FTE's) necessary to support the statutorily driven regulatory functions of the state radiation program and in particular the X-ray machine certification program. Additionally, any decrease in staff would expectedly diminish the functionality of



the program and increase the turnaround time for facility and individual registrations.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

It is believed that there are no less costly or less intrusive methods for providing funding for the radiation machine registration program. As discussed in item 6 below, an alternative approach to the proposed annual radiation machine facility registration fee would be to raise the per label fee by 60% (\$30) rather than the proposed 20% (\$10) increase. Such an approach would rely on the existing infrastructure and would not likely need additional support or new activities for billing or maintenance. Such an approach would however affect and effectively penalize the larger facilities disproportionately since such facilities have a greater number of machines that must be inspected more frequently. Smaller facilities with the average number of machines (~4) would pay slightly smaller amounts (~\$23 per year) under a higher (\$30 per) label fee scenario (with no registration fee) compared to a moderate (\$10) label fee increase plus the annual \$50 registration fee. The exact fee differences for any given facility depend upon machine inspection frequencies and number of machines. Since it is not tied to machine inspection frequency (which is related to risk), the annual facility registration fee is intended to provide balance to the overall fee structure for all facilities and will provide a more near term, stable funding source for the program.

Similarly, with the radioactive materials licensing program, it is believed there are no less costly or less intrusive methods for providing funding for the activities conducted by the radioactive materials unit. Under Colorado's agreement with NRC, adequate funding must be ensured to maintain compatibility and agreement state status. Failure to provide adequate funding could result in the state program deferring to federal control, and thus resulting in federal fees that are on average 40-50% higher than current Colorado fees.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

One alternative to the proposed annual facility registration fee is to make up the budget deficit through an increase in label fees which would use the existing infrastructure for label sales. Presently, radiation machine certification label sales to privatized Qualified Inspectors are the primary source of revenue the Radiation Program receives for maintaining the registry and tracking of the approximate 5,200 radiation machine facilities in Colorado. To achieve the same funding level in lieu of the new proposed nominal facility registration fee of \$50, the per-machine label fee would have to increase to an estimated \$80 per label (an additional \$30 per label above the current \$50 per label cost) rather than the currently proposed increase of \$10 per label plus annual registration fee.

The approach to raise label fees alone would disproportionately impact the largest facilities (typically larger medical centers and hospitals) that would ultimately pay more due to a larger number of machines to certify and register and because typically large facilities have machines on 1, 2 and 3-year inspection cycles (while many small businesses' machines are on a 3-year inspection cycle). Medical facilities and hospitals which range from small community and rural medical centers to large hospitals typically have an average of 11 machines per facility, with the largest facilities having over 100 radiation producing machines. This disproportionate impact is why the Division determined that a new "flat rate"

facility registration fee would provide for a more equitable and balanced approach to fees.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

The analysis for the proposed rule change and fee increases considered multiple sources of information and data, including the current (full-year) consumer price index data, evaluation of current FY 2014 revenue data, and projected revenue and costs for 2015 and beyond. All sources of income were considered in the evaluation, along with the current radiation machine and facility data, and radioactive materials license data.

#### SHORT-TERM CONSEQUENCES

The short-term consequences of failing to implement the proposed regulatory and fee changes for the radiation machines program would likely be a reduction in the current staffing levels below the current ~4.0 FTE required for maintaining the current tracking and registration of Colorado's 14,500+ X-Ray machines at 5,200+ facilities. This would expectedly result in reduced customer service due to an increase in the turnaround time for facility registrations and information updates; label sales; response to registrant inquiries, questions, and support; and may reduce the timeliness of current inspections and data. Inspection of the 100+ mammography machines as performed by state inspectors may lag or be compromised, and would thus fail to meet the annual FDA prescribed inspections.

The short-term consequences of failing to implement the proposed regulatory and fee changes for the radioactive materials program would likely result in a reduction in the current staffing levels below the current FTE required for the licensing and inspection of Colorado's 325+ specific radioactive materials facilities and regulatory program. This would expectedly increase the turnaround time for issuance of new licenses, license actions, renewal licenses, response to licensee inquiries, questions and support, response to incidents, allegations and inspections. Such delays could also compromise or otherwise negatively impact Colorado's ability to maintain its agreement state status with NRC.

#### LONG-TERM CONSEQUENCES

The long-term consequences of failing to implement the proposed regulatory and fee changes for the radiation machines program would be the potential elimination of the state radiation machine regulatory program in Colorado. As there is no equivalent federal regulatory program or agency for regulating radiation machines, the program would be left inoperable and thus the safety of members of the public would potentially be compromised due to a lack of radiation machine inspections/certifications and regulatory oversight and a lack of ensuring that personnel operating and servicing machines would be unchecked. Elimination of the radiation machine program would be contrary to the requirements of current state statute.

The long-term consequences of failing to implement the proposed regulatory and fee changes for the radioactive materials program would potentially result in elimination of the agreement state program in Colorado and deferral of the program to the federal government (US NRC). Based upon current federal fee data for radioactive materials licenses, regulated entities would pay approximately 45+% more per year in annual licensing fees, higher hourly rates, and would not benefit from a local regulatory

agency presence. Elimination of the radioactive materials program would be contrary to the requirements of current state statute.

## STAKEHOLDER COMMENTS

### for Amendments to

### 6 CCR 1007-1, Radiation Control, Part 12, Fees for Radiation Control Services and Part 2, Registration of Radiation Machines, Facilities, and Services

The following individuals and/or entities were included in the development of these proposed rules:

Notification of the opportunity to comment on the proposed changes to Part 12 and Part 2 were sent on October 30, 2014 to a total of approximately 6,000+ entities via US Mail and/or email.

The entities represented:

- Approximately 5,200 X-Ray facilities (registrants);
- Approximately 124 Radiation Machine Qualified Inspectors;
- Approximately 176 Radiation Machine Service Companies/Qualified Experts;
- Approximately 425 Radiation Machine Limited Scope Operators;
- Approximately 325 specific radioactive materials licensees;
- Approximately 418 general radioactive materials licensees;
- Approximately 159 "other stakeholders" representing individuals who have specifically signed up to receive notification of any proposed radiation regulation changes and who represent a wide variety of interests, including: x-ray registrants, radioactive materials licensees; private citizens; private companies; professional organizations; and activist groups; and
- Seven professional healing arts related organizations including: Colorado Hospital Association; Colorado Medical Society; Colorado Radiological Society; Colorado Dental Association; Colorado Chiropractic Association; Colorado Veterinary Medical Association; and Rocky Mountain Oncology Society. These entities were notified via U.S. mail and email where available. Some organizations also passed the information along to their members.

In addition to the opportunity for written comment, stakeholders were provided with the opportunity to participate in three stakeholder meetings held in November (prior to the conclusion of the comment period). A total of 12 stakeholders participated in these meetings either in-person or via phone.

This rulemaking does not include a local government mandate. EO5 does not apply.

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

The notice of the rulemaking hearing was posted on the Department website and was sent via email or U.S. Mail to all of the aforementioned stakeholders on or about January 08, 2015.

The notice included a link/URL address to the Radiation Program website:

<https://www.colorado.gov/pacific/cdphe/radiation-regulations-development-part-12> which included a copy of the rulemaking hearing notice, a summary of the proposed changes for both Part 12 and Part 2, copies of the draft rules, and the tentative dates for both the request for rulemaking and final rulemaking before the Board of Health.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The Department has engaged licensees and minimal concern has been raised; licensees are aware that Department services are provided for substantially less than what the NRC would charge if the CDPHE program was no longer financially viable. Similarly, the x-ray machine registrants were also engaged. As outlined in the table below, the greatest concern is from small businesses - predominantly those in the Dentistry, Veterinary, and Chiropractic fields - that are concerned about the proposed increase in X-ray fees and feel that they are not warranted or fully justified.

COMMENTS ASSOCIATED WITH THOSE IN FAVOR OF THE PROPOSED CHANGES	RESPONSE / RESOLUTION
A radioactive materials licensee radiation safety officer in support of the proposed fee and regulatory changes commented that the program is more educational than punitive and that it stays current with advances in medicine with respect to regulatory knowledge and oversight.	N/A
COMMENTS ASSOCIATED WITH THOSE OPPOSED TO THE PROPOSED CHANGES	RESPONSE / RESOLUTION
A commenter representing hospitals throughout Colorado suggested that the Department consider the impacts on smaller, rural hospitals as impacts on such facilities may be greater.	<p>While the radiation program recognizes that all facilities are not the same size nor are the impacts the same, there is not a current method to fully realize the size of any facility to make fee adjustments based on size. The radiation program fees are typically based on the type of use, the associated risks, and the effort expended by the Department in regulating such facilities.</p> <p>The radioactive materials licensing process allows licensees to apply for small entity status and reduced fees. Four hospital facilities are currently approved as small entity licensees.</p> <p>No change was made to the rule as a result of the comment.</p>
A Qualified Inspector (QI) registrant expressed concern that QI's would be made into "bill collectors" and would be responsible for collecting the proposed facility registration fee.	<p>If implemented, any new facility registration fee will be collected directly by the Department and not by the privatized qualified inspectors.</p> <p>No change was made to the rule as a result of the comment.</p>
A QI registrant raised the issue that the proposed shift from biennial (2 year) registration to an annual (yearly) registration for QI's would result in additional effort for both the QI and the Department.	<p>The department recognizes that some additional, more frequent effort will have to be expended by both the program and the QI's if the registration process is changed to an annual frequency. It is believed that the annual cycle will provide a more stable and consistent income stream needed to support the regulatory program. Additionally requiring annual registration will allow for better tracking and auditing of QIs.</p>

	<p>Some offset of the efforts expended is expected due to implementation of new data management systems. Development of these systems is currently underway.</p> <p>No change was made to the rule as a result of the comment.</p>
<p>A Service Company registrant expressed concern over when the current registrations would expire and that some loss of their registration term would occur upon implementation of the proposed annual cycle.</p>	<p>While all details of implementation of the proposed annual registration cycle for Service Company (and other) registrants has not been fully developed, the Department intends to implement the annual renewal cycle upon expiration of the current registrations. For example, a Service Company registration, that currently expires in 2016, would not begin the annual renewal cycle until the current registration expires in 2016.</p> <p>No change was made to the rule as a result of the comment.</p>
<p>A general licensee express concern over the proposed increase in fees in light of all of the other fees that are paid to or otherwise required by the state (as a whole) and the combined regulatory impact of such a fee change.</p>	<p>The annual fee for general licensees is currently \$100 per year. The radiation program believes the proposed \$20 per year increase in this annual fee is moderate and necessary to maintain the regulatory program. In the event the state of Colorado did not retain the general license program, it would automatically defer to federal control under the US Nuclear Regulatory Commission (NRC). Current NRC fees for general licensing is \$400 per year, which is over 3 times higher than the proposed \$120 annual fee.</p> <p>No change was made to the rule as a result of the comment.</p>
<p>Several commenter's (a radioactive materials licensee and multiple x-ray registrants) commented that other sources of funding should be sought, and in particular, that monies obtained through enforcement actions (administrative penalties) should be redirected to the radiation program rather than the state general fund.</p>	<p>Current statutory language in the Colorado Radiation Control Act (law) specifically identifies that funds (administrative penalties) obtained through escalated enforcement be directed to the states' general fund. This is consistent with the laws regulating other regulatory programs within the hazardous materials division. Since this is a requirement of state law, a change to this process would require an act of the legislature.</p> <p>While staff and attorney time and effort is expended by the radiation program in pursuit of escalated enforcement actions, it is believed that overall this approach is in the best interest of the regulated community and supports a balanced approach to the program. By not receiving the administrative penalty funds back into the program, it removes the "incentive" to pursue enforcement actions in cases where it is not truly warranted from a regulatory perspective.</p>

	No change was made to the rule as a result of the comment.
An employee of a radioactive materials licensee commented on the proposed rule and fee changes indicating uncertainty as to whether fees would be changing or increasing for radioactive materials licensees.	<p>The radiation program is proposing fee changes for all entities it regulates, including both radioactive materials licensees and radiation machine registrants. The proposed increases for existing fees for all regulated entities ranges from 16%-25%.</p> <p>No change was made to the rule as a result of the comment.</p>
<p>An organization representing dentists throughout Colorado commented that:</p> <ul style="list-style-type: none"> <li>- The financial impact is that fees nearly double for dental offices and dentists, who are typically small businesses, have a harder time absorbing increased costs relative to larger facilities;</li> <li>- A disproportionate amount of the fee increases are being paid by the dental profession in light of the fact that dental machines present less risk. Estimates indicate that dentistry would fund ~25% of the total fee increase;</li> <li>- The radiation program should review costs and ensure fees charged are aligned with program expenses;</li> <li>- Perhaps the facility or label fee could be tiered based on the complexity of equipment.</li> </ul>	<p>The Program is proposing a new annual registration fee of \$50/facility regardless of the number of machines the facility uses. This fee will cover the costs of maintaining facility information. The average dentist has 4 machines that are subject to a 3 year inspection cycle. The current annual label cost for the average dentist is \$67 dollars. The proposed label fee changes, plus the proposed new registration fee (applicable to all facilities) would increase the annual cost for the average dentist to \$130 (a nominal monetary increase of \$63) annually.</p> <p>The department believes that radiation program fees are reasonable in relation to the radiation control services provided to the dentistry field. Of the ~14,500+ machines regulated by the X-ray program, ~63% (~9,000+) are used in dental facilities. About half (~50 %) of the registered X-ray facilities are dental facilities. Accounting for the 3 year inspection cycle for dental machines, over 40% (~3,066) of the (7,328) inspection/certification reports received and processed in a year by the program are for dental facilities.</p> <p>While the routine radiation machine inspection program is conducted by independent privatized inspectors (known as “qualified inspectors”) approved by the department, the department is responsible for overall monitoring and regulatory follow up. With the exception of the certification label fee, the radiation program does not set or dictate the amount charged by the qualified inspector for the inspections and therefore it is a “free market” program. Typical monitoring activities related to the 14,500+ machines in Colorado include maintaining and verifying changes in facility information (the legal authorized owner, contact information, location, etc.); changes in radiation machine information (machine or component replacement, disposition of equipment, etc.); per facility and machine inspection data; and inspection follow up. Smaller facilities and operations tend to relocate more frequently resulting in more modifications to track.</p>

	<p>It is unclear how the “complexity” of the radiation machine could be established and used in a tiered fee structure or what the benefit of such a structure would have from a radiation safety perspective that is not otherwise addressed. The inspection frequency (which varies from 1-3 years) is directly associated with the risk presented by the machine. Higher risk machines (volumetric dental, fluoroscopy, computed tomography, etc.) are inspected more frequently. Since a new label is placed on a machine during each inspection, the consideration of risk is already tied to the label fee. Facilities using higher risk machines pay for inspections and inspection labels more often than do facilities having lower risk machines.</p>
<p>Multiple comments (~16) were received from numerous x-ray registrants representing Dentists, Chiropractors, and Veterinarians. The questions and comments expressed were somewhat similar in nature and addressed the following issues, concerns, and questions:</p> <ul style="list-style-type: none"> <li>- The proposed fee changes are unreasonable and excessive and present hardships for small businesses and medical practitioners who already face multiple fees and taxes, and the fee increases make no sense;</li> <li>- While some fee increase may be justified, it was felt that both the annual facility registration fee and increasing the per label fee was not justified;</li> <li>- It is already costly to have the (x-ray) machines certified by the (qualified) inspectors;</li> <li>- Why are fee increases proposed despite the reduction in participants (in the regulated program) and the fact there are fewer x-ray machines producing radioactive waste/materials;</li> <li>- Prior regulatory changes (related to sensitometry) several years ago has resulted in patients having to go to higher priced large facilities for imaging resulting in higher health care costs;</li> <li>- The radiation program should work “smarter”, and spot and cut waste, making (fee) adjustments only as the market will bear, and seek other methods to make up the budget, including a reduction in staffing, raising other fees, or making other program changes;</li> <li>- Why are fees being increased 48-75%?</li> <li>- The department has not identified the health problems necessary to justify the fee increases;</li> <li>- The process used for finding/registering ambulatory (mobile) veterinarian radiation</li> </ul>	<p>The Radiation Program considers the increase in fees as a serious matter that it does not take lightly, especially in consideration of the impacts to small businesses and consumers in Colorado. However, as indicated in the summary information available online and as presented during the stakeholder meetings, the proposed increases are needed to support the regulatory program which helps to ensure that only qualified individuals own, operate, service, or inspect radiation producing machines in accordance with state law and that the output of such machines is consistent with federal requirements. The radiation program is seeking to maintain its existing radiation control services.</p> <p>Historically, there has been an upward trend in the number of radiation machines in Colorado. Data for the prior 4 years (2010-2014) indicates a 1 to 2 % net increase in the number of radiation machines registered each year (a net addition of 1700 machines were registered for the period 2010-2014). This amounts to ~300+ new radiation machines at 90+ new facilities each year on average. As economic conditions in Colorado continue to improve, it is expected that this number will remain the same or increase slightly.</p> <p>The radiation program believes that the proposed increase in radiation machines label and registration application fees are balanced, reasonable, and justified in light of the fact that the fees for machine certification labels - the primary source of income supporting the radiation machine regulatory program - have not changed for 13 years despite the net increase in registration and tracking of 100-300 new radiation machines each year over the past several years. The proposed nominal \$10 increase per label will make up for some budgetary deficit, but it will not address the entire shortage. In order to make up the entire</p>



<p>users (registrants) is flawed as many have not heard of Colorado's (radiation machine) regulatory program and may not be registered or impacted by these fees. Because of this, your agency is only targeting a small percentage of (the veterinary) radiation users in the field which is unfair;</p> <ul style="list-style-type: none"> <li>- Fees for radiation machines should be based upon use of the machine (-number of x-rays taken);</li> <li>- Medical reimbursement rates tend to be going down and any increase in fees or changes to certification periods for medical practitioners presents a hardship.</li> </ul> <p>Some commenter's indicated that no increase in fees should be proposed while another suggested that only the \$10 increase in label fee be proposed.</p>	<p>budget shortfall through label sales, the label cost would have to increase by at least \$30 per label, thus monetarily penalizing larger facilities to a greater degree. While a nominal \$50 annual facility registration fee is newly proposed, such a flat "per facility" fee provides some balance and does not unduly penalize larger facilities who currently pay more in label fees due to the larger number of machines they possess and the increased inspection frequency required for such facilities. Larger facilities may have some greater ability to "absorb" increased costs than do smaller facilities, the majority of healing arts registrants are small in size and typically possess only a few machines which must be certified. Although it is dependent upon the type of use of the machine, the majority of smaller facilities pay less per facility in label fees each year as the inspection frequencies are typically 3 years rather than the 1-year inspection frequency required for the vast majority of machines at most larger medical facilities.</p> <p>Some commenter's questioned why there was an increase in fees when there was a reduction in the number of regulated entities and there are fewer x-ray machines producing radioactive materials (due to "conversion to digital systems"). It should be noted that the conversion from film-based to digital x-ray systems does not result in or create radioactive materials. Radiation producing machines used in diagnostic applications are not radioactive nor do they create or produce any type of radioactive wastes or radioactive materials. The number of radiation producing machines has increased over the past several years, thus requiring additional regulatory efforts.</p> <p>The costs associated with machine inspections are neither set nor controlled by the radiation program or the state. The qualified inspector program is a privatized, "free market" system and the certification/inspection fees they charge are set by each individual inspector. Only the certification label fee and the inspection frequency is set by the state through regulation. There are no proposed changes to the inspection frequencies with this rulemaking. As only QIs may purchase certification labels, the label fee is typically passed along to the end user registrant as part of the inspection.</p> <p>The radiation program continues to seek ways to improve its services to the regulated community, including being responsive to inquiries and questions; providing exemptions from certain requirements; maintaining a small staffing level relative to the number of radiation machines and facilities and other entities regulated under the</p>
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	<p>program; and continuing efforts to improve the effectiveness and efficiency of the program in cost effective ways.</p> <p>The radiation machine regulatory program is primarily a pre-emptive, preventative program intended to ensure that radiation machines are installed and serviced by qualified, monitored personnel; that they are owned and operated by qualified personnel; and the machine output is consistent with manufacturer specifications and such inspections are performed only by trained and qualified personnel. The program is most commonly notified of new radiation machines in use through registered service companies who have installed the equipment. Failure of such service companies to obtain registration or to notify the department of new installations is in conflict with state regulations.</p> <p>A commenter suggested that fees for radiation machines should be tied to the amount of use of the machine which relates to risk. To some degree, more “risk based” fees are already in place in the form of more frequent inspections. The risk is tied to the type of radiation machine, radiation output and potential harm rather than the amount of use, which could only be provided by the user. The program does not track or require tracking of any specific machines use.</p> <p>A commenter questioned a change to the inspection or certification frequency. No changes to the inspection frequency for medical practitioners or any other radiation machine user or radiation machine is being proposed. The proposed radiation machine facility registration fee does not change the machine inspection frequency.</p> <p>No change was made to the rule as a result of the comments.</p>
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Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

The Department has proposed a fee structure that treats entities needing radiation control services equitably. Fees are tiered based upon the type of use, risk of materials/machine output involved, and efforts necessary to regulate the facility. Fees are also tiered based upon the number of radiation machines housed within a facility. Specifically, the annual registration fee, coupled with the increased label fee, creates a balance between the minimum cost to provide radiation control services to a facility using radiation machines and the increased workload associated with tracking and ensuring the safety of multiple machines within a facility. Though the increase in fees impacts business and health care provider costs,

a majority of stakeholders have not indicated that the increase will create an undue burden on workers, customers or patients. This is consistent with the increased annual cost of \$629,922 being allocated across 5,375 entities. The increase cost is justified as it directly advances worker and patient safety.

**DRAFT 1 12/08/14**

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**Hazardous Materials and Waste Management Division**

**RADIATION CONTROL - FEES FOR RADIATION CONTROL SERVICES**

**6 CCR 1007-1 Part 12**

*[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

**Adopted by the Board of Health February 18, 2015.**

**PART 12: FEES FOR RADIATION CONTROL SERVICES**

**12.1 Purpose and Scope.**

**12.1.1 Authority.**

12.1.1.1 Rules and regulations set forth herein are adopted pursuant to the provisions of Sections 25-1-108, 25-1.5-101(1)(k) and 25-1.5-101(1)(l), and 25-11-104(6), CRS.

**12.1.2 Basis and Purpose.**

12.1.2.1 A statement of basis and purpose accompanies this part and changes to this part. A copy may be obtained from the Department.

**12.1.3 Scope**

12.1.3.1 The regulations in this part establish fees for radiation control services rendered by the Department as authorized by the Act.

**12.1.4 Applicability.**

12.1.4.1 The regulations in this part apply to radiation control services for a person who is an applicant for, or holder of, a:

(1) Specific radioactive material license or a general radioactive material license, issued pursuant to Part 3:

(a) Except for a person who applies for or holds a specific license exempted in 12.3.

(2) Registration, issued pursuant to Part 2.

12.1.4.2 The regulations of this part also apply to a request for:

(1) Evaluation of a sealed source and/or device containing radioactive material;

(2) A special project review that the Department completes or makes whether or not in conjunction with a license application on file or which may be filed, and/or

(3) Any other service as specified.

**12.1.5 Published Material Incorporated by Reference.**

**Comment [JJ1]:**

**EDITORIAL NOTE 1:** ALL COMMENTS (SUCH AS THIS ONE) SHOWN IN THE RIGHT SIDE MARGIN OF THIS DRAFT RULE ARE FOR INFORMATION PURPOSES ONLY TO PROVIDE ADDITIONAL INFORMATION AND TO AID THE READER IN UNDERSTANDING THE PROPOSED CHANGE DURING THE DRAFT REVIEW PROCESS.

THESE COMMENTS ARE **NOT** PART OF THE RULE AND ALL COMMENTS WILL BE DELETED PRIOR TO FINAL SUBMISSION TO THE COLORADO SECRETARY OF STATE'S OFFICE FOR FINAL PUBLISHING IN THE COLORADO CODE OF REGULATIONS.

EDITORIAL NOTES WITHIN THE **BODY** OF THE RULE ARE FOR INFORMATION PURPOSES ONLY AND ARE NOT CONSIDERED PART OF THE RULE.

**Comment [JJ2]:**

This date reflects the tentative rulemaking date, pending approval by the Board of Health.

12.1.5.1 Published material incorporated in Part 12 by reference is available in accord with Part 1, Section 1.4.

## **12.2 Definitions.**

12.2.1 As used in this part, these terms have the definitions set forth as follows.

"Abandoned application" means any application filed with the Department for which the Department has in writing requested additional information needed to process the application and the Department does not receive a written reply from the applicant within forty-five (45) days after the Department's most recent written request for additional information.

"Anniversary Date" means that date upon which annual fees shall be due and payable. Anniversary Date is determined as the last day of the month corresponding to the month listed as the licensee's expiration date.

"Application" means any request filed with the Department for a permit, license, approval, exemption, exception, certificate, registration, other permission, or for any other service.

"Full cost fee" means a fee based on reasonable and actual professional staff time and appropriate contractual support services expended for certain radiation control activities as specified in Appendix 12A.

"Inspection" (routine or non-routine) means:

- (1) "Routine inspection" designed to evaluate the licensee's or registrant's activities within the context of the licensee or registrant having primary responsibility for protection of the public and environment.
- (2) "Non-routine inspection" in response or reaction to an incident, allegation, follow up to inspection deficiencies, inspection to determine implementation of safety issues including radioactive waste control services pursuant to CRS Sections 25-11-101–305 and Sections 24-60-2201–2212 and these regulations. A non-routine or reactive inspection has the same purpose as the routine inspection.

"Low-Level Radioactive Waste Access Approval" means those reviews and on-site evaluations necessary to assure waste generator compliance with low-level radioactive waste site access criteria as established by the Rocky Mountain Low-Level Radioactive Waste Board (the Board) or by a compact with which the Board has an agreement to accept low-level radioactive waste from Colorado or by a state with which the Board has an agreement to accept low-level radioactive waste from Colorado or by any state or site to which a Colorado generator ships low-level radioactive waste.

"Open Records Act" means the Colorado Open Records Act, CRS 24-72-201 et seq.

"Permanent location" means, for purposes of Part 12, a location where radioactive material is used and/or stored for more than 180 cumulative total days in any calendar year.

"Special Project" means a request submitted to the Department for review for which a fee is not otherwise specified in this part. Examples of special projects include, but are not limited to, early site reviews, consultation, emergency response plan reviews, assessment of responses to Department orders, contamination surveys in response to license termination or relocation, and financial surety reviews.

## **12.3 Exemptions.**

12.3.1 No fees pursuant to 12.4.1 through 12.4.5 shall be required for a radioactive materials license authorizing the use of source material as shielding only in devices and containers, provided that all other licensed radioactive material in the device or container will be subject to the fees described in Appendix 12A.

80 12.3.2 Application for Exemptions.

81 12.3.2.1 The Department may, upon application by an interested person, or upon its own  
82 initiative, grant such exemptions from the requirements of this part for good cause as it  
83 determines are authorized by law and are otherwise in the public interest.

84 12.3.2.2 Applications for exemption under this section may include activities such as, but  
85 not limited to, the use of licensed materials for educational or noncommercial public  
86 displays or scientific collections.

87 **12.4 Specific Radioactive Materials Licenses and Radiation Machine Registrations.**

**Comment [JJ3]:**  
The section title is expanded to address the added language specific to radiation machine facility registrations.

88 12.4.1 Application Fees **for Specific Radioactive Materials Licenses.**

89 12.4.1.1 The application fee for a new radioactive materials license not subject to full cost  
90 fees must accompany the application when it is filed.

91 (1) Except for a license subject to full cost fees, no application for a new license, for  
92 the reinstatement of an expired license, or for an application for amendment to a  
93 materials license that would place the licensee in a higher fee category will be  
94 accepted for filing or processed prior to payment of the full amount specified in  
95 Appendix 12A.

96 (2) Except for a license subject to full cost fees, an application fee is not required for  
97 a routine or renewal license amendment that does not involve a change in fee  
98 category.

99 (3) Applications for which fee payment is required and no remittance is received may  
100 be returned to the applicant.

101 12.4.1.2 An application for renewal of a license not subject to full cost fees which has  
102 expired and for which a renewal was not timely filed pursuant to 3.17.2 shall be  
103 accompanied by a reinstatement fee of \$~~400~~465.

**Comment [JJ4]:** The fee specified here is increased, consistent with other proposed fee changes throughout Part 12.

104 12.4.1.3 Application fees for new radioactive materials licenses, renewals, amendments,  
105 other required approvals and requests for dismantling, decommissioning and termination  
106 of licensed activities, that are subject to the full cost fees are payable upon notification by  
107 the Department.

108 12.4.1.4 All licensing fees will be charged irrespective of the Department's disposition of  
109 the application or a withdrawal of the application.

110 12.4.1.5 Abandoned Applications.

111 (1) In the case of an abandoned amendment application, if the licensee desires to  
112 submit a new amendment application for the same or similar authorization, the  
113 reapplication shall be accompanied by a \$~~100~~115 reapplication fee.

114 (2) In the case of an abandoned new license application, if the applicant desires to  
115 submit a new application, then the applicant is subject to the application fee  
116 specified in Appendix 12A.

117 12.4.1.6 Expedited License Review.

118 (1) An hourly rate for direct staff time associated with the review of an application will  
119 be assessed for an expedited review.

120 (2) This expedited license review fee only applies when, by consent of the applicant,  
121 a licensing request is taken out of the date order in which it was received.

12.4.2 Fee for Radiation Machine Facility Registration for Radiation Control Services

12.4.2.1 The fee for a new radiation machine facility registration not subject to full cost fees must accompany the application when it is filed.

(1) Except for a registration subject to full cost fees, no application for a new registration, or for the reinstatement of an expired registration will be accepted for filing or processed prior to payment of the full registration application amount specified in Appendix 12A.

(2) Except for a radiation machine facility registration subject to full cost fees, a fee is not required for an amendment to registration information, except as otherwise specified in Appendix 12A.

(3) Applications for which fee payment is required and no remittance is received may be returned to the applicant.

12.4.2.2 An application for renewal of a registration not subject to full cost fees which has expired and for which a renewal was not timely filed pursuant to 2.4.1.1 shall be accompanied by a reinstatement fee of \$50.

12.4.2.3 All radiation machine facility fees will be charged irrespective of the Department's disposition of the application or a withdrawal of the application.

12.4.2.4 Abandoned Applications.

(1) In the case of an abandoned new registration application, or an abandoned registration amendment application, then the applicant is subject to the application fee specified in Appendix 12A.

12.4.32 Termination Fees for Licensees.

12.4.32.1 Applications for license termination for licensees not subject to full cost fees will not be subject to fees provided that the licensee notifies the Department and requests termination pursuant to 3.16, as appropriate, and provided that there is no decommissioning or decontamination involved subsequent to the request for termination. Licensees subject to full cost fees shall be billed for the full cost of the review of the application for termination.

12.4.32.2 Staff time spent in obtaining information which is not provided by the licensee as required by 3.16.6 and 3.16.7 when decontamination is necessary, or in supervising the licensee's decommissioning or decontamination of the site, will be billed at the Department's hourly rate.

12.4.32.3 The charges for staff time billed under 12.4.32 are payable upon notification by the Department.

12.4.43 Inspection Fees for Radioactive Materials Licensees and Radiation Machine Facility Registrants.

12.4.43.1 Inspection costs include reasonable and actual preparation time, time on site, documentation time, any associated contractual service costs, and time involved in the processing and issuance of a notice of violation or ~~civil~~administrative penalty.

12.4.43.2 Fees for inspection of licensees and registrants not subject to full cost fees:

(1) Fees for routine inspections are included in the annual fee and will not be charged separately.

**Comment [JJ5]:**

This section is added to address a new proposed registration fee and process for facilities using radiation machines. Currently, all facilities using a radiation producing (X-Ray) machine must be registered with the Department, but do not pay a registration fee.

The proposed language/process will require each facility possessing a radiation producing (X-Ray) machine to pay a proposed \$50 annual registration fee and provide an updated registration form to the Department. The proposed annual radiation machine facility registration fee will be a "flat rate" fee per facility regardless of the number of radiation machines possessed by the facility.

**Comment [JJ6]:**

The section title is modified for clarity, since the current section language already addresses both (radioactive materials) licensees and (radiation machine) licensees.

Other than the proposed "across the board" (~16-25%) fee increases throughout the rule, there are no new fees associated with routine or non-routine inspections.

**Comment [JJ7]:**

In accordance with the terminology used in Part 13, the terminology is changed. Administrative penalties are administered by the Department whereas civil penalties are administered by a court of law.

- (2) Fees for all non-routine inspections will be assessed on a per-inspection basis and are payable upon notification by the Department.

12.4.43.3 Fees for inspections of licensees and registrants subject to full cost fees:

- (1) Inspection fees will be assessed to recover the full cost for each specific inspection as specified in Appendix 12A, including licensee-specific performance reviews and assessments, evaluations, and incident investigations.
- (2) Inspection fees for licensees and registrants subject to full cost fees, and for inspections other than routine, are due upon notification by the Department.

12.4.54 Annual fees.

**Radiation Machine Facility Registrants**

**12.4.5.1 Persons who hold radiation machine facility registrations shall pay an annual fee.**

- (1) The licensee or registrant shall pay the fee in Appendix 12A for each registration the person holds on the date the annual fee is due.
- (2) If a person holds more than one registration, the fee will be the cumulative total of the annual fee for all registrations held by that person.

**Comment [JJ8]:**

This new section is added to address the requirements associated with the proposed annual fee and registration process for radiation producing (X-Ray) machine facilities.

The proposed annual radiation machine facility registration fee will be a "flat rate" fee per facility regardless of the number of radiation machines possessed by the facility.

**Specific Radioactive Materials Licensees**

**12.4.5.24.1** Persons who hold specific radioactive materials licenses shall pay an annual fee.

- (1) The licensee shall pay the fee in Appendix 12A for each license the person holds on the date the annual fee is due.
- (2) If a person holds more than one license, the fee will be the cumulative total of the annual fee for all licenses held by that person.
- (3) For those **radioactive materials** licenses that authorize more than one activity (e.g., human use and irradiator activities), annual fees will be assessed for each category applicable to the license.
- (4) Persons with **radioactive materials** licenses authorizing permanent, multiple locations of use and/or storage that are separated by more than one mile shall increase the annual fee by 75 percent for the second location; 50 percent for the third location; and 25 percent for each additional location of use.

**12.4.5.34.2** A **specific radioactive materials** licensee required to pay an annual fee may qualify as a small entity.

- (1) If a licensee qualifies as a small entity and provides the Department with the proper certification, the licensee may pay reduced annual fees as shown in Table 12-1.

**Comment [JJ9]:**

The title of the table is modified for clarity, as small entity status applies only to specific radioactive materials licensees.

**Comment [JJ10]:** The Size Standard is adjusted, consistent with that used by the US NRC in 10 CFR 171.16.

**Comment [JJ11]:**

The small entity fee is adjusted upward by ~20%, consistent with other increases in the proposed rule. The proposed small entity fee is equal to the lowest fee charged by NRC for such small entities/businesses.

In 2014, Colorado had approximately 64 specific licensees who qualified for small entity status, of which 30% fall into the lowest fee category.

**Table 12-1: Small Entity Fees Applicable to Specific Radioactive Materials Licensees**

Entity Category	Size Standard	Maximum Annual Fee Per Licensed Category
Small businesses not engaged in manufacturing and small not for profit organizations	<del>\$485,500</del> \$500,000 – \$7,000,000 gross annual receipts	1/2 Annual Fee or <del>\$600,500</del> \$600,500, whichever is greater
	Less than	<del>\$ 600,500</del> \$ 600,500



	\$ <del>485</del> 50,000 gross annual receipts	
Manufacturing entities that have an annual average of 500 employees or less	35 to 500 employees	1/2 Annual Fee or \$ <del>600</del> 500, whichever is greater
	Less than 35 employees	\$ <del>600</del> 500
Small governmental jurisdictions (including cities, counties, towns, townships, villages, school districts, special districts or publicly supported educational institutions)	20,000 – 50,000 population	1/2 Annual Fee or \$ <del>600</del> 500, whichever is greater
	Less than 20,000 population	\$ <del>600</del> 500
Educational institutions that are not state or publicly supported, and have 500 employees or less	35 to 500 employees	1/2 Annual Fee or \$ <del>600</del> 500, whichever is greater
	Less than 35 employees	\$ <del>600</del> 500

- (2) A licensee who seeks to establish status as a small entity for purpose of paying the annual fees required under this section shall file a certification statement with the Department.
- (3) The licensee shall file the required "radioactive materials licensee certification of small entity status," Department Form R-62, for each license under which the licensee is billed.
- (4) For the licensee to be granted small entity status by the Department, a completed Form R-62, signed by the owner of the entity or an official empowered to act on behalf of the entity, shall accompany each application for a new license and each annual fee.
- (5) The licensee shall provide a new Department Form R-62, signed by the owner of the entity or an official empowered to act on behalf of the entity, within thirty days from receipt of such a request from the Department.
- (6) Failure to file a small entity certification, or to provide an updated certification upon the request of the Department, could result in the denial of the fee reduction that might otherwise be granted.
- (7) A licensee who is a subsidiary of a large entity does not qualify as a small entity for purposes of Table 12-1.

12.4.5.44-3 An annual management fee shall be charged for **radioactive materials licensees**~~persons~~ operating in the State under reciprocity as follows:

- (1) Any radioactive material brought into the state for use under reciprocity shall pay a reciprocal recognition fee equal to 75 percent of the appropriate annual fee in Appendix 12A.
- (2) Reciprocal fees shall be due and payable prior to entry into the state.
- (3) An acknowledgement of fee payment will be provided by the Department. The acknowledgement of fee payment shall be retained by the licensee and maintained with the pertinent documents prescribed in 3.24.1.1(6).
- (4) Reciprocal recognition fees shall not be transferred or refunded.
- (5) Reciprocal recognition fees shall expire 12 months from the issue date<sup>2</sup>.

<sup>2</sup> Pursuant to 3.24, an out-of-state licensee may operate in Colorado under reciprocity for no more than 180 cumulative total days in any calendar year.

12.4.5.54-4 Payment of Annual Fees.

**Radiation Machine Facility Registrants**

(1) The annual fees shall be due and payable each year by the expiration date. The annual fees are not refundable except in those cases where the Department has determined that the fee is not required.

(2) Annual fees shall be charged and payment required for any registrant that has not terminated their registration on or before the expiration date.

**Specific Radioactive Materials Licensees**

(1) The annual fees shall be due and payable each year on the anniversary date. The annual fees are not refundable except in those cases where the Department has determined that the fee is not required.

(2) Annual fees shall be charged and payment required for any license that has not been terminated on or before the anniversary date or for which a request for termination has not been submitted to the Department pursuant to 3.16.7.

**12.5 General Licenses.**

12.5.1 Persons who hold general licenses under the following categories shall pay an annual fee:

12.5.1.1 Depleted uranium in industrial products and devices authorized under 3.5.5;

12.5.1.2 Possession of more than 1 kilogram of source material other than depleted uranium for shielding under 3.5;

12.5.1.3 Measuring, gauging and controlling devices under 3.6.4; and

12.5.1.4 In vitro licenses under 3.6.9.

12.5.2 The basis for the annual fee is to cover the Department's cost associated with the regulation and control of these sources, and to cover the Department's administrative costs for those generic activities directly related to the regulation of materials licensees.

12.5.3 Fees for general licenses are listed in Appendix 12A and shall be payable every July 1, for as long as the license remains in effect.

12.5.4 Fees for inspection of licenses, authorized under 3.5.5 and 3.6, that are based on the full cost of the inspection are payable upon notification by the Department.

**12.6 Special Project Fees.**

12.6.1 Fees for special projects are assessed for the full cost of the review, as specified in Appendix 12A.

12.6.1.1 Special project fees shall be based on reasonable and actual professional staff time.

12.6.1.2 Appropriate contractual support services expended for certain radiation control activities will also be included.

12.6.2 Fees for special projects are payable upon notification by the Department.

**12.7 Low-Level Radioactive Waste Access Approval Fees.**

**Comment [JJ12]:**

This new subsection is added, consistent with prior section changes pertaining to the proposed annual radiation producing (X-Ray) machine facility registration process/fee.

267 12.7.1 Fees for services required for low-level radioactive waste access approval are payable upon  
268 notification by the Department.

269 **SEARCH, REVIEW, DUPLICATION AND SPECIAL SERVICE FEES**

270 **12.8 ~~Reserved~~Search, Review, Duplication and Special Service Fees.**

271 12.8.1 ~~Search, Review, and Special Service Fees.~~

272 ~~12.8.1.1 — The Department charges fees for search, duplication and review.~~

273 ~~(1) — The Department may assess fees even when no Department records are located as a result of~~  
274 ~~the search or when Department records that are located as a result of the search are not~~  
275 ~~disclosed; and,~~

276 ~~(2) — If the public record is a result of a computer output, other than word processing, the fee for a~~  
277 ~~copy, printout, or other photograph thereof may be based on recovery of the actual incremental~~  
278 ~~costs of providing the electronic services and products together with a reasonable portion of the~~  
279 ~~costs associated with building and maintaining the information system.~~

280 ~~(a) — The Department shall charge a reasonable fee, if, in response to a specific request, it has~~  
281 ~~performed a manipulation of data so as to generate a record in a form not used by the State.~~  
282 ~~Such fees shall not exceed the actual cost of manipulating the said data and generating the said~~  
283 ~~record in accordance with the request.~~

284 ~~(b) — Persons making subsequent requests for the same or similar records may be charged a fee not in~~  
285 ~~excess of the original fee.~~

286 ~~12.8.1.2 — The Department shall charge requesters who request the following services for the direct~~  
287 ~~costs of the service:~~

288 ~~(1) — Certifying that records are true copies; or~~

289 ~~(2) — Sending records by special methods, such as Express Mail, package delivery service, etc.~~

290 ~~12.8.2 Duplication Fees.~~

291 ~~12.8.2.1 — The charge for duplicating records shall be computed on the basis of Department's direct~~  
292 ~~costs, including both the cost of staff and the cost of the actual copy.~~

293 ~~12.8.2.2 — Copyrighted material shall not be reproduced in violation of the copyright laws.~~

294 ~~12.8.3 Fees for Search and Review of Department Records by Department Personnel.~~

295 ~~12.8.3.1 — The Department shall charge the following hourly rates for search and review of~~  
296 ~~Department records by Department personnel:~~

297 ~~(1) — Clerical search, review, and duplication at a rate that is equivalent to the actual cost of an~~  
298 ~~Administrative Assistant III at the five-year rate;~~

299 ~~(2) — Professional search, review, and duplication at a rate that is equivalent to the actual cost of an~~  
300 ~~Environmental Protection Specialist II at the five-year rate; and~~

301 ~~(3) — Senior management search, review, and duplication at a rate that is equivalent to the actual cost~~  
302 ~~of an Environmental Protection Specialist V at the five-year rate.~~

303 ~~12.8.4 Search and Duplication Provided Without Charge.~~

304 ~~12.8.4.1 — The Department may not bill any requester for fees if the cost of collecting the fee would~~  
305 ~~be equal to or greater than the fee itself.~~

**Comment [JJ13]:**

For consistency with state requirements relating to fees for duplication of records, the contents of section 12.8 are deleted.

The fees received by the program for duplication and related services are minimal.

~~12.8.4.2 — The Department may aggregate requests in determining search and duplication to be provided without charge as provided in 12.8.4.1, if the Department finds a requester, or multiple requesters acting in concert, has filed multiple requests for only portions of a Department record or similar Department records for the purpose of avoiding charges.~~

~~12.8.5 — Assessment of Fees.~~

~~12.8.5.1 — If the request is expected to require the Department to assess fees in excess of \$25 for search and/or duplication, the Department shall notify the requester that fees will be assessed unless the requester has indicated in advance the willingness to pay fees as high as estimated.~~

~~12.8.5.2 — In the notification, the Department shall include the estimated cost of search fees and the nature of the search required and estimated cost of duplicating fees.~~

~~12.8.5.3 — The Department will encourage requesters to discuss with the Department the possibility of narrowing the scope of the request with the goal of reducing the cost while retaining the requester's original objective.~~

~~12.8.5.4 — If the fee is determined to be in excess of \$250, the Department may require payment at the time the information is provided.~~

~~12.8.6 — Requests for Waiver or Reduction of Fees.~~

~~12.8.6.1 — The Department shall collect fees for searching for, reviewing, and duplicating Department records, except as provided in 12.8.4, unless a requester submits a request in writing for a waiver or reduction of fees and the Department approves such request.~~

~~(1) — To assure that there will be no delay in the processing of Open Records Act requests, the request for a waiver or reduction of fees should be included in the initial Open Records Act request letter.~~

~~12.8.6.2 — Each request for a waiver or reduction of fees must be addressed to the Director, Hazardous Materials and Waste Management Division, Colorado Department of Public Health and Environment.~~

~~12.8.6.3 — A person requesting the Department to waive or reduce search, review, or duplication fees shall:~~

~~(1) — Describe the purpose for which the requester intends to use the requested information;~~

~~(2) — Explain the extent to which the requester will extract and analyze the substantive content of the Department record;~~

~~(3) — Describe the nature of the specific activity or research in which the Department records will be used and the specific qualifications the requester possesses to utilize information for the intended use in such a way that it will contribute to public understanding;~~

~~(4) — Describe the likely impact on the public's understanding of the subject as compared to the level of understanding of the subject existing prior to disclosure;~~

~~(5) — Describe the size and nature of the public to whose understanding a contribution will be made;~~

~~(6) — Describe the intended means of dissemination to the general public;~~

~~(7) — Indicate if public access to information will be provided free of charge or provided for an access fee or publication fee; and~~

~~(8) — Describe any commercial or private interest the requester or any other party has in the Department records sought.~~

346 ~~12.8.6.4 The Department may waive or reduce the fee if, from information provided with the~~  
347 ~~request for Department records made under 12.8.6.3, the Department determines that disclosure~~  
348 ~~of the information in the Department records is for a public purpose, including public agency~~  
349 ~~program support, nonprofit activities, journalism, and academic research, and is not primarily in~~  
350 ~~the commercial interest of the requester.~~

351 ~~12.8.6.5 In making a determination regarding a request for a waiver or reduction of fees, the~~  
352 ~~Department may consider the following factors:~~

353 ~~(1) If disclosure is likely to contribute significantly to public understanding of government operations~~  
354 ~~or activities;~~

355 ~~(2) If, and the extent to which, the requester has a commercial interest that would be furthered by the~~  
356 ~~disclosure of the requested Department records; and~~

357 ~~(3) If the magnitude of the identified commercial interests of the requester is sufficiently large, in~~  
358 ~~comparison with the public interest in disclosure, that disclosure is primarily in the commercial~~  
359 ~~interest of the requester.~~

## 360 **12.9 Partial Payment of Fees.**

361 12.9.1 In the case of services, which are subject to full cost fees, the Department may bill monthly for  
362 any service rendered.

## 363 **12.10 Method of Payment.**

364 12.10.1 Approved credit cards, checks, drafts or money orders for payment of fees shall be payable to the  
365 Colorado Department of Public Health and Environment.

## 366 **12.11 Schedule of Fees for Materials Licenses and Other Radiation Control Services.**

367 12.11.1 Applicants for radioactive materials licenses, for services related to radiation machines, for other  
368 regulatory services and holders of materials licenses shall pay fees for the categories of services  
369 listed in Appendix 12A.

370 12.11.1.1 License applications received prior to the effective date of this rule shall be billed  
371 in accordance with the fee schedule, as updated by the hourly rate in effect at that time  
372 the service is performed.

373 12.11.2 For each service provided subject to full cost fees, records will be maintained of time spent, using  
374 reasonable accounting procedures by at least 15 minute intervals. A summary of time spent on  
375 any activity will be provided upon request.

376 12.11.3 The Department will ~~review and evaluate~~~~adjust~~ all fees, **costs**, and the cost per person-hour  
377 every ~~two (2) years~~~~six (6) months~~ from the effective date of this part ~~based on relative to~~  
378 **expenses and the most recent** Denver-Boulder-Greeley Consumer Price Index (**CPI**) for All  
379 Urban Consumers ~~(January 1, 2007 summary). An updated version of the fee schedule will be~~  
380 ~~available upon request.~~

381 ~~12.11.4 Every two (2) years from the effective date of these regulations, the Department will review the~~  
382 ~~fees and the Department's costs.~~

383 12.11.4.1 If the ~~adjusted CPI~~ **changes by more than ten (10) percent, or where fees and**  
384 **costs exceed revenues** for any categories ~~differ by more than ten percent (10%) over a~~  
385 **single review cycle or multiple review cycles since the last effective date of this**  
386 **part**, the Department will propose ~~a revised fee(s)~~ **a revised fee(s)** to the Board of Health for ~~those the~~  
387 **applicable** categories **or fees**.

## 388 **12.12 Failure by Applicant or Licensee to Pay Prescribed Fee.**

### **Comment [JJ14]:**

Original sections 12.11.3 – 12.11.4 are revised to clarify the frequency and process by which fees are reviewed and modified by the Department as the current language lacks clarity.

389 12.12.1 In any case where the Department finds that an applicant, **registrant**, or a licensee has failed to  
390 pay a prescribed fee for any licensing, **registration** or inspection activities required in this Part,  
391 the Department will not process any application, may suspend or revoke any license **or**  
392 **registration** involved pursuant to **2.10, or** 3.23 and may request action pursuant to CRS 25-11-  
393 107(4). Staff time expended in collection of any fee not paid within sixty (60) days of the date due  
394 will be billed at the Department's hourly rate.

395 **12.13 Penalties.**

396 12.13.1 A \$20.00 penalty will be assessed for checks returned to the Department due to insufficient  
397 funds.

398 12.13.2 Late Payments.

399 12.13.2.1 A penalty shall be assessed to any person whose fee is collected by a collection  
400 agency.

401 12.13.2.2 The penalty shall be equal to the fee charged by the collection agency.

402 **12.14 Severability.**

403 12.14.1 The provisions of this regulation are severable, and if any provisions or the application of the  
404 provisions to any circumstances is held invalid, the application of such provision to other  
405 circumstances, and the remainder of this regulation shall not be affected thereby.  
406

**PART 12, APPENDIX 12A: SCHEDULE OF FEES FOR RADIOACTIVE MATERIALS LICENSEES,  
FOR SERVICES RELATED TO RADIATION MACHINES, AND FOR OTHER SERVICES<sup>3,4,5,6</sup>**

3 Applications for new licenses, applications to reinstate expired or terminated licenses, except those subject to fees assessed at full costs, must be accompanied by the prescribed application fee for each category.

4 Application for amendments to licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

5 Renewal fees – Fees for applications for renewal of materials licenses will not be charged, except that fees for applications for renewal of licensees subject to full cost fees are due upon notification by the Department.

6 Inspection Fees: (a) Fees for routine inspections at locations authorized by the license or reciprocity permit will not be charged, except that routine inspections subject to full cost fees are due upon notification by the Department. (b) Separate charges will be assessed for each non-routine inspection which is performed. The frequency of routine inspections are those established in the Hazardous Materials And Waste Management Division Radiation Program Inspection and Enforcement Manual, and will be in accord with the frequencies established by the U.S. Nuclear Regulatory Commission for similar types of licenses.

**CATEGORY 1 - SPECIAL NUCLEAR MATERIAL<sup>7,8</sup>**

7 Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

8 Applications for new licenses that cover both special nuclear material and radioactive material and/or naturally occurring and accelerator produced material in sealed sources for use of gauging devices will pay the appropriate processing fee for category 1.C only.

1.A Licenses for possession and use of 200 grams or more of plutonium in unsealed form or 350 grams or more of U-235 in unsealed form or 200 grams or more of U-233 in unsealed form. This includes applications to terminate licenses as well as licenses authorizing possession only.

NOTE: Colorado does not license this category of license.

Application Not Applicable

Annual Fee Not Applicable

Inspection Not Applicable

1.B Licenses for receipt and storage of spent fuel at an independent spent fuel storage installation (ISFSI).

NOTE: Colorado does not license this category of license.

Application Not Applicable

Annual Fee Not Applicable

Inspection Not Applicable

1.C Licenses for possession and use of special nuclear material in sealed sources contained in devices used in industrial measuring systems including x-ray fluorescence analyzers.

Application \$ ~~1,380~~**1,600**

Annual Fee \$ ~~1,380~~**1,600**

Inspection \$ ~~1,080~~**1,255**

1.D All other special nuclear material licenses, except licenses authorizing special nuclear material in unsealed form in combinations that would constitute a critical quantity.

Application \$ ~~3,300~~**3,830**

Annual Fee \$ ~~3,300~~**3,830**

**Comment [JJ15]:**

The Radiation Program is proposing an “across the board” fee increase ranging from approximately 16-25 %, consistent with changes in the Consumer Price Index (Denver-Boulder-Greeley area; 2013). This fee increase is reflected in the proposed changes shown through Appendix 12A. The proposed fee change is to address the rising costs of the Department in providing Radiation Control related services.

All values have been rounded to the nearest \$5 increment for consistency.

448 | Inspection \$ ~~2,445~~2,835

449 **CATEGORY 2 - SOURCE MATERIAL**

450 2.A1 Licenses for possession and use of source material for refining uranium mill concentrates to  
451 uranium hexafluoride.

452 NOTE: Colorado does not license this category of license.

453 Annual Fee Not Applicable

454 Licensing and Inspection Not Applicable

455 2.A2 Licenses for possession and use of source material in recovery operations such as milling, in situ  
456 leaching, heap-leaching, ore buying stations, ion exchange facilities and in processing of ores  
457 containing source material for extraction of metals other than uranium or thorium, including  
458 licenses authorizing the possession of byproduct waste material (tailings) from source material  
459 recovery operations, and licenses authorizing decommissioning, reclamation or restoration  
460 activities as well as licenses authorizing the possession and maintenance of a facility in a standby  
461 mode.  
462

463 2.A2 Class I License includes mill licenses issued for the extraction of uranium from uranium  
464 ore.

465 | Annual Fee \$ ~~94,300~~109,390

466 Licensing and Inspection Full Cost

467 2.A2 Class II License includes solution mining licenses (in-situ and heap leach) issued for the  
468 extraction of uranium from uranium ores including research and development licenses.

469 | Annual Fee \$ ~~79,005~~91,645

470 Licensing and Inspection Full Cost

471 2.A2 Class III "Other" license includes licenses for extraction of metals, heavy metals, and rare  
472 earths.

473 | Annual Fee \$ ~~29,900~~34,685

474 Licensing and Inspection Full Cost

475 2.A3 Licenses that authorize the receipt of uranium waste tailings generated by milling operations from  
476 other persons for possession and disposal, except those licenses subject to the fees in category  
477 2.A2 or category 2.A4.

478 | Annual Fee \$ ~~58,190~~67,500

479 Licensing and Inspection Full Cost

480 2.A4 Licenses that authorize the receipt of uranium waste tailings generated by milling operations from  
481 other persons for possession and disposal incidental to the disposal of the uranium waste tailings  
482 generated by the licensee's milling operations, except those licenses subject to the fees in  
483 category 2.A2.

484 | Annual Fee \$ ~~9,200~~10,670

485 Licensing and Inspection Full Cost



486	2.B	Licenses for possession and use of source material for shielding.
487		Application \$ <del>690</del> 800
488		Annual Fee \$ <del>690</del> 800
489		Inspection \$ <del>1,220</del> 1,415
490	2.C	All other source material licenses.
491		Application \$ <del>11,040</del> 12,805
492		Annual Fee \$ <del>11,040</del> 12,805
493		Inspection \$ <del>4,520</del> 5,245
494	<b>CATEGORY 3 - BYPRODUCT MATERIAL, NATURALLY OCCURRING AND ACCELERATOR</b>	
495	<b>PRODUCED RADIOACTIVE MATERIAL</b>	
496	3.A	Licenses of broad scope for possession and use of radioactive material issued pursuant to 3.11
497		for processing or manufacturing of items containing radioactive material for commercial
498		distribution.
499		Application \$ <del>20,470</del> 23,745
500		Annual Fee \$ <del>20,470</del> 23,745
501		Inspection \$ <del>8,655</del> 10,040
502	3.B	Other licenses for possession and use of radioactive material for processing or manufacturing of
503		items containing radioactive material for commercial distribution.
504		Application \$ <del>5,290</del> 6,135
505		Annual Fee \$ <del>5,290</del> 6,135
506		Inspection \$ <del>2,530</del> 2,935
507	3.C	Licenses authorizing the processing or manufacture and distribution or redistribution of
508		radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing
509		radioactive material.
510		Application \$ <del>12,305</del> 14,275
511		Annual Fee \$ <del>12,305</del> 14,275
512		Inspection \$ <del>2,530</del> 2,935
513	3.D	Licenses authorizing distribution of radiopharmaceuticals, generators, reagent kits, and/or
514		sources or devices not involving processing of radioactive material.
515		Application \$ <del>3,910</del> 4,535
516		Annual Fee \$ <del>3,910</del> 4,535
517		Inspection \$ <del>1,300</del> 1,510
518	3.E	Licenses for possession and use of radioactive material in sealed sources for irradiation of
519		materials where the source is not removed from its shield (self-shielded units).

520		Application \$ <del>3,195</del> <b>3,705</b>
521		Annual Fee \$ <del>3,195</del> <b>3,705</b>
522		Inspection \$ <del>1,380</del> <b>1,600</b>
523	3.F	Licenses for possession and use of less than 370 TBq (10,000 Ci) of radioactive material in
524		sealed sources for irradiation of materials where the source is exposed for irradiation purposes.
525		Application \$ <del>5,795</del> <b>6,720</b>
526		Annual Fee \$ <del>5,795</del> <b>6,720</b>
527		Inspection \$ <del>2,150</del> <b>2,495</b>
528	3.G	Licenses for possession and use of 370 TBq (10,000 Ci) or more of radioactive material in sealed
529		sources for irradiation of materials where the source is exposed for irradiation purposes. This
530		category includes under water irradiators for irradiation of materials where the source is not
531		exposed.
532		Application \$ <del>20,930</del> <b>24,280</b>
533		Annual Fee \$ <del>20,930</del> <b>24,280</b>
534		Inspection \$ <del>4,140</del> <b>4,800</b>
535	3.H	Licenses issued to distribute items containing radioactive material which requires device review to
536		persons exempt from the licensing requirements of Part 3.
537		Application \$ <del>3,195</del> <b>3,705</b>
538		Annual Fee \$ <del>3,195</del> <b>3,705</b>
539		Inspection \$ <del>1,300</del> <b>1,510</b>
540	3.I	Licenses issued to distribute items containing radioactive material or quantities of radioactive
541		material which do not require device evaluation to persons exempt from the licensing
542		requirements of Part 3 except specific licenses authorizing redistribution of items that have been
543		authorized for distribution to persons generally licensed by the U.S. Nuclear Regulatory
544		Commission or an Agreement State.
545		Application \$ <del>4,600</del> <b>5,335</b>
546		Annual Fee \$ <del>4,600</del> <b>5,335</b>
547		Inspection \$ <del>1,530</del> <b>1,775</b>
548	3.J	Licenses issued to distribute items containing radioactive material which require sealed source
549		and/or device review to persons generally licensed. This category does not include specific
550		licenses authorizing redistribution of items that have been authorized for distribution to persons
551		generally licensed under Part 3.
552		Application \$ <del>2,095</del> <b>2,430</b>
553		Annual Fee \$ <del>2,095</del> <b>2,430</b>
554		Inspection \$ <del>1,425</del> <b>1,655</b>
555	3.K	Licenses issued to distribute items containing radioactive material or quantities of radioactive
556		material that do not require sealed and/or device review to persons generally licensed. This

557		category does not include specific licenses authorizing redistribution of items that have been
558		authorized for distribution to persons generally licensed under Part 3.
559		Application \$ <del>1,380</del> <b>1,600</b>
560		Annual Fee \$ <del>4,380</del> <b>1,600</b>
561		Inspection \$ <del>770</del> <b>895</b>
562	3.L	Licenses of a broad scope for possession and use of radioactive material for research and
563		development which do not authorize commercial distribution.
564		Application \$ <del>10,005</del> <b>11,605</b>
565		Annual Fee \$ <del>10,005</del> <b>11,605</b>
566		Inspection \$ <del>3,520</del> <b>4,085</b>
567	3.M	Other licenses for possession and use of radioactive material for research and development
568		which do not authorize commercial distribution.
569		Application \$ <del>4,405</del> <b>5,110</b>
570		Annual Fee \$ <del>4,405</del> <b>5,110</b>
571		Inspection \$ <del>1,755</del> <b>2,035</b>
572	3.N	Licenses that authorize services for other licensees, except (1) licenses that authorize calibration
573		and/or leak testing services only are subject to the fees specified in fee category 3.Q, and (2)
574		licensees that authorize waste disposal services are subject to the fees specified in fee
575		Categories 4.A, 4.B., or 4.C.
576		Application \$ <del>4,795</del> <b>5,560</b>
577		Annual Fee \$ <del>4,795</del> <b>5,560</b>
578		Inspection \$ <del>2,070</del> <b>2,400</b>
579	3.O	Licenses for possession and use of radioactive material for industrial radiography operations.
580		Application \$ <del>12,535</del> <b>14,540</b>
581		Annual Fee \$ <del>12,535</del> <b>14,540</b>
582		Inspection \$ <del>2,680</del> <b>3,110</b>
583	3.P	Portable gauge radioactive material licensees.
584		Application \$ <del>2,405</del> <b>2,790</b>
585		Annual Fee \$ <del>2,405</del> <b>2,790</b>
586		Inspection \$ <del>1,680</del> <b>1,950</b>
587	3.Q	All other specific radioactive material licensees, except those in fee categories 1, 2, 3.A through
588		3.P, and 4.A. through 9.D.
589		Application \$ <del>2,405</del> <b>2,790</b>

590 Annual Fee \$ ~~2,405~~**2,790**

591 Inspection \$ ~~1,680~~**1,950**

592 **3.S Licenses for production of accelerator-produced radionuclides.**

593 Application \$ ~~14,275~~**14,275**

594 Annual Fee \$ ~~14,275~~**14,275**

595 Inspection \$ ~~2,935~~**2,935**

**Comment [JJ16]:**

This is a new fee category which is intended to better describe and categorize this type of licensee and used of material consistent with the approach used by NRC.

Colorado currently has 3 radioactive materials licensees which would be moved into this fee category. These licensees currently pay an annual fee amount equivalent to the "3.C" fee category. Under the proposed revisions, these entities would pay a fee equivalent to the amount in the proposed (revised) 3.C fee category.

596 **CATEGORY 4 - WASTE HANDLERS**

597 4.A Licenses specifically authorizing the receipt of waste byproduct material, source material, special  
598 nuclear material, or naturally occurring and accelerator produced material from other persons for  
599 the purpose of commercial disposal by land burial by the licensee; or licenses authorizing  
600 contingency storage of low-level radioactive waste at the site of nuclear power reactors; or  
601 licenses for treatment or disposal by incineration and transfer of packages to another person  
602 authorized to receive or dispose of waste material.

603 Annual Fee Not Applicable<sup>9</sup>

604 <sup>9</sup> There are no existing Colorado licenses in these fee categories. Once Colorado issues a license for these categories, the  
605 Department will consider establishing an annual fee for that type of license.

606 Licensing and Inspection Full Cost

607 4.B Licenses specifically authorizing the receipt of waste byproduct material, source material, special  
608 nuclear material, or naturally occurring and accelerator produced material from other persons for  
609 the purpose of packaging or repackaging the material. The licensee will dispose of the material by  
610 transfer to another person authorized to receive or dispose of the material.

611 Application \$ ~~9,775~~**11,340**

612 Annual Fee \$ ~~9,775~~**11,340**

613 Inspection \$ ~~2,530~~**2,935**

614 4.C Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source  
615 material, special nuclear material, or naturally occurring and accelerator produced material from  
616 other persons. The licensee will dispose of the material by transfer to another person authorized  
617 to receive or dispose of the material.

618 Application \$ ~~7,395~~**8,580**

619 Annual Fee \$ ~~7,395~~**8,580**

620 Inspection \$ ~~2,830~~**3,285**

621 **CATEGORY 5 - WELL LOGGING**

622 5.A Licenses for possession and use of byproduct material, source material, special nuclear material,  
623 or naturally occurring and accelerator produced material for well logging, well surveys, and tracer  
624 studies other than field.

625 Application \$ ~~8,795~~**10,200**

626 Annual Fee \$ ~~8,795~~**10,200**

627 | Inspection \$ ~~2,830~~**3,285**

628 | 5.B Licenses for possession and use of byproduct material for field flooding tracer studies.

629 | Annual Fee \$ ~~40,395~~**12,060**

630 | Licensing and Inspection Full Cost

631 | **CATEGORY 6 - NUCLEAR LAUNDRIES**

632 | 6.A Licenses for commercial collection and laundry of items contaminated with radioactive material, source material, special nuclear material, or naturally occurring and accelerator produced material.

633 |

634 |

635 | Application \$ ~~46,905~~**19,610**

636 | Annual Fee \$ ~~46,905~~**19,610**

637 | Inspection \$ ~~4,140~~**4,800**

**Comment [JJ17]:**

Colorado does not currently have any licensees in this fee category.

638 | **CATEGORY 7 - HUMAN AND VETERINARY USE OF RADIOACTIVE MATERIAL**

639 | 7.A Licenses issued for human or veterinary use of radioactive material, source material, special nuclear material, or naturally occurring and accelerator produced material in sealed sources contained in teletherapy devices.

640 |

641 |

642 | Application \$ ~~43,915~~**16,140**

643 | Annual Fee \$ ~~43,915~~**16,140**

644 | Inspection \$ ~~2,370~~**2,750**

645 | 7.B Licenses of broad scope issued to medical institutions or two or more physicians or veterinarians authorizing research and development including human and/or veterinary use of radioactive material, source material, special nuclear material, or naturally occurring and accelerator produced material except material in sealed sources.

646 |

647 |

648 |

649 | Application \$ ~~24,150~~**28,015**

650 | Annual Fee \$ ~~24,150~~**28,015**

651 | Inspection \$ ~~6,325~~**7,335**

652 | 7.C Other licenses issued for human or veterinary use of radioactive material, source material, and/or naturally occurring and accelerator produced material except material in sealed sources contained in teletherapy devices.

653 |

654 |

655 | Application \$ ~~4,600~~**5,335**

656 | Annual Fee \$ ~~4,600~~**5,335**

657 | Inspection \$ ~~2,220~~**2,575**

658 |

659 | **CATEGORY 8 - CIVIL DEFENSE**

660 | 8.A Licenses for possession and use of radioactive material for civil defense activities.

661 | Application \$ ~~1,095~~**1,270**

**Comment [JJ18]:**

Colorado does not currently have any licensees in this fee category

662 Annual Fee \$ ~~4,095~~1,270

663 Inspection \$ ~~1,840~~2,135

664 **CATEGORY 9 - DEVICE, PRODUCT, OR SEALED SOURCE SAFETY EVALUATION**

665 9.A Safety evaluation of devices or products containing byproduct material, source material, special  
666 nuclear material, or naturally occurring and accelerator produced material except reactor fuel  
667 devices, for commercial distribution.

668 Annual Fee \$ ~~5,795~~6,720

669 Evaluations Full Cost

670 9.B Safety evaluation of devices or products containing radioactive material, source material, special  
671 nuclear material, or naturally occurring and accelerator produced material manufactured in  
672 accordance with the unique specifications of, and for use by a single applicant, except reactor  
673 fuel devices.

674 Annual Fee \$ ~~5,795~~6,720

675 Evaluations Full Cost

676 9.C Safety evaluation of sealed sources containing byproduct material, source material, special  
677 nuclear material, or naturally occurring and accelerator produced material, except reactor fuel, for  
678 commercial distribution.

679 Annual Fee \$ ~~4,690~~1,960

680 Evaluations Full Cost

681 9.D Safety evaluation of sealed sources containing byproduct material, source material, special  
682 nuclear material, or naturally occurring and accelerator produced material, manufactured in  
683 accordance with the unique specifications of, and for use by a single applicant, except reactor  
684 fuel.

685 Annual Fee \$ ~~575~~665

686 Evaluations Full Cost

687 **CATEGORY 10 - TRANSPORTATION OF RADIOACTIVE MATERIAL**

688 Note: Colorado does not license this category of license.

689 **CATEGORY 11 - REVIEW OF STANDARDIZED SPENT FUEL FACILITIES**

690 Note: Colorado does not license this category of license.

691 **CATEGORY 12 - SPECIAL PROJECTS**

692 12.A Special Projects and all uses of radioactive material which are not included in any other category.

693 Application Full Cost

694 Annual Fee Full Cost

695 Inspection Full Cost

696 **CATEGORY 13 - SPENT FUEL STORAGE COSTS**

697 Note: Colorado does not license this category of license.

698 **CATEGORY 14**

699 14.A Byproduct material, source material, special nuclear material, naturally occurring or accelerator  
700 produced radioactive material licenses and other approvals authorizing decommissioning,  
701 decontamination, reclamation or site restoration activities.

702 Annual Fee Not Applicable<sup>10</sup>

703 10 Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while  
704 they are licensed to operate.

705 Licensing and Inspection Full Cost

706 **CATEGORY 15 - EMERGENCY RESPONSE**

707 15.A Emergency response requiring over 10 person-hours in any 12 consecutive months.

708 Full Cost

709 15.B Emergency response planning and exercises.

710 Full Cost<sup>11</sup>

711 11 Fees will be charged only when service is requested or required by an authorized person outside of the Department who has  
712 legal authority to make such requests.

713 **CATEGORY 16 - ANALYTICAL PROCEDURES**

714 Full Cost

715 **CATEGORY 17 - GENERAL LICENSES**<sup>12</sup>

716 12 Fees are for each license at each facility. Fees for general licenses are annual fees, and are due July 1 each year. Non-routine  
717 inspections of general licensees related to (1) exposures to individuals; or (2) release of radioactive materials in excess of limits  
718 established in Part 4 of these regulations.

719 17.A Source material, gauges and other similar devices pursuant to 12.5.1.1 through 12.5.1.3.

720 Annual Fee \$ ~~400~~115

721 Inspection Full Cost

722 17.B In vitro pursuant to 12.5.1.4.

723 Annual Fee \$ ~~50~~60

724 Inspection Full Cost

725 **CATEGORY 18 - LOW-LEVEL RADIOACTIVE WASTE ACCESS APPROVAL**

726 Full Cost

727 **CATEGORY 19 - HOURLY RATE**<sup>13</sup>

728 \$ 152

729 13 For any service provided by the Department in accord with ~~this part, 12.11.2 and 12.11.3-A~~ a statement will be sent to the  
730 registrant indicating the actual costs incurred.

731 **CATEGORY 20 - TRANSFER OF RECORDS TO DEPARTMENT PURSUANT TO 4.40 THROUGH 4.50**

732 Per box for indexed paper records submitted in state storage boxes

733 \$ ~~4045~~

734 For records not indexed and/or requiring repackaging in standard storage boxes

735 Full Cost

736 **CATEGORY 21 - RADIATION MACHINES ENFORCEMENT ACTION**

737 Maximum fee per each radiation machines certification enforcement action<sup>14,15</sup>: \$ ~~4,330~~1,545

738 14 Any registrant that fails the requirements of 2.5.1, or does not correct any violation in accordance with the compliance schedule  
739 established in ~~2.5.2-32.9.1.2~~, shall be subject to a Department enforcement action at the current hourly rate and/or maximum fee.  
740 The Department shall charge enforcement fees, which may include inspection fees for the inspection of radiation machines and  
741 facilities that have been determined, by either a qualified inspector or by the Department, to be in noncompliance with these  
742 regulations and with the certification frequency. These fees do not include penalties imposed under Part 13.

743 15 This represents the maximum fee that may be incurred for the Department enforcement actions of each radiation machine and/or  
744 facility determined to be in violation with these regulations by either a qualified inspector or by the Department.

**Comment [JJ19]:**  
Due to the previous renumbering/reorganization of Part 2, the section referenced is updated.

745 **CATEGORY 22 - QUALIFIED INSPECTOR, QUALIFIED EXPERT, OR COMPANIES PROVIDING**  
746 **RADIATION MACHINE SERVICING AND SERVICES**

747 Maximum fee per registration every ~~year~~2-years: \$ ~~160~~100<sup>16,17</sup>

748 16 The qualified inspector **and qualified expert** registration fee is an individual fee. The servicing and services registration fee is a  
749 company fee.

750 17 ~~The annual fee is \$80 and is payable every two years in the amount of \$160.~~ This fee is non-refundable in the event that the  
751 application is not approved by the Department.

**Comment [JJ20]:**  
Category 22 fees have always included the “qualified expert” category as part of the service company category. The added language is intended to clarify this.

752 **CATEGORY 23 – REVIEW OF RADIATION MACHINE PROVISIONAL MAMMOGRAPHERY**  
753 **CERTIFICATION APPLICATION**

754 Maximum fee per each certification review or renewal: \$ ~~50~~60

755 **CATEGORY 24 – REVIEW OF ADEQUATE TRAINING FOR RADIATION MACHINE LIMITED SCOPE**  
756 **OPERATORS, BONE DENSITOMETRY OPERATORS, AND COMPUTED TOMOGRAPHY**  
757 **OPERATORS AND SERVICE COMPANY ENGINEER<sup>18</sup>**

758 Maximum fee per each acceptance review: \$ ~~50~~60

759 18 ~~The fee for service company engineers is a “per application” fee for any number of service company engineers to be~~  
760 ~~authorized to work under a service company registration.~~

761 **CATEGORY 25 - RADIATION MACHINE CERTIFICATION LABEL ISSUED BY A QUALIFIED**  
762 **INSPECTOR**

763 Required fee for each certification label issued to a registrant: \$ ~~50~~60

764 **CATEGORY 26 - RADIATION MACHINE FACILITY REGISTRATION FEE FOR RADIATION CONTROL**  
765 **SERVICES**

766 **Maximum annual registration fee per facility using a radiation machine: \$ 50**

767

768 **EDITOR'S NOTES**

769 6 CCR 1007-1 has been divided into separate parts for ease of use. Versions prior to 04/01/2007 are  
770 located in the first section, 6 CCR 1007-1. Prior versions can be accessed from the All Versions list on the  
771 rule's current version page. To view versions effective on or after 04/01/2007, select the desired part of  
772 the rule, for example 6 CCR 1007-1 Part 01 or 6 CCR 1007-1 Part 10.



773 **History**

774 Part 12 entire rule eff. 03/02/2009.

775 Part 12 Rules 12.1.4, 12.3.1.1(2), Appendix A, Categories 23, 24 eff. 04/30/2011.

CONCURRENT WITH THE PROPOSED CHANGES TO PART 12 ("FEES FOR RADIATION CONTROL SERVICES"), THE FOLLOWING SECTION OUTLINES THE PROPOSED CHANGES TO 6 CCR-1007, PART 2 ("REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES"). NOTE THAT UNAFFECTED SECTIONS ARE OMITTED FROM THE PROPOSED DRAFT CHANGES.

DRAFT 2 02/03/15

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Hazardous Materials and Waste Management Division

STATE BOARD OF HEALTH

RADIATION CONTROL - REGISTRATION OF RADIATION MACHINES, FACILITIES AND SERVICES

6 CCR 1007-1 Part 02

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Adopted by the Board of Health December 17, 2014 February 18, 2015

[ \* \* \* = Indicates omission of unaffected rules]

\* \* \*

REQUIREMENTS FOR DEPARTMENT APPROVAL AND/OR REGISTRATION

2.4 State of Colorado Authorization or Approval Recognized by the Department is Required for Each Category Designated in This Section.

2.4.1 Registration of a Facility.

2.4.1.1 Each person possessing or in the process of coming into the possession of a radiation machine facility shall:

(1) Be registered with the Department prior to using a radiation producing machine at the facility;

(2) ~~Complete and~~ Before the facility registration expiration date, submit ~~an a~~ complete application for registration on the applicable Department R-4 series Form, and include all of the information required by the form and any accompanying instructions. The facility shall:

(a) Designate a radiation safety officer who meets the applicable requirements of Appendix 2A to be responsible for overall radiation protection for the facility; and

(b) Document that a written shielding design has been:

(i) Completed in accordance with Parts 6, 8, or 9 of these regulations, as applicable, prior to any radiation machine installation; and

(ii) Retained on file at the facility for the life of the facility.

(c) Pay the radiation machine facility registration fee for radiation control services indicated by Part 12, Category 26. The radiation machine facility registration fee is not required for registration updates required by 2.4.6.5 unless the update is submitted less than thirty (30) days prior to the registrant's expiration date.

2.4.1.2 As prescribed by 6.3.3.3 for a healing arts screening program, registrants shall complete and submit a Healing Arts Screening application including all of the information required by Part 6, Appendix 6F ).

Comment [JJ21]:

EDITORIAL NOTE 1: ALL COMMENTS (SUCH AS THIS ONE) SHOWN IN THE RIGHT SIDE MARGIN OF THIS DRAFT RULE ARE FOR INFORMATION PURPOSES ONLY TO PROVIDE ADDITIONAL INFORMATION AND TO AID THE READER IN UNDERSTANDING THE PROPOSED CHANGE DURING THE DRAFT REVIEW PROCESS.

THESE COMMENTS ARE **NOT** PART OF THE RULE AND ALL COMMENTS WILL BE DELETED PRIOR TO FINAL SUBMISSION TO THE COLORADO SECRETARY OF STATE'S OFFICE FOR FINAL PUBLISHING IN THE COLORADO CODE OF REGULATIONS.

EDITORIAL NOTES WITHIN THE **BODY** OF THE RULE ARE FOR INFORMATION PURPOSES ONLY AND ARE NOT CONSIDERED PART OF THE RULE.

EDITORIAL NOTE 2: THE PROPOSED AMENDMENT TO THIS (PART 2) RULE ARE IN SUPPORT OF CONCURRENT PROPOSED CHANGES TO PART 12 (FEES FOR RADIATION CONTROL SERVICES). THE PROPOSED DRAFT IS BASED ON THE FINAL PART 2 RULE WHICH BECAME EFFECTIVE IN AUGUST 2014 AND DO NOT REFLECT OTHER CHANGES WHICH MAY BE IN-PROCESS AND NOT YET FINALIZED.

EDITORIAL NOTE 3: THOSE ITEMS SHOWN IN YELLOW HIGHLIGHT HAVE CHANGED FROM THE PREVIOUS DRAFT (DRAFT 1 DATED 11/2/14 AS PRESENTED DURING THE DECEMBER 17, 2014 BOARD OF HEALTH MEETING.

Comment [JJ22]: Consistent with the proposed, concurrent changes to Part 12 (fees for radiation control services), additional language is added to introduce an annual facility registration fee.

2.4.1.3 In addition to the other requirements of 2.4, any research using radiation machines on humans shall be approved by an Institutional Review Board (IRB).

#### 2.4.2 Registration as a Service Company.

2.4.2.1 Each person who is engaged (or offers to engage) in the business of selling, leasing, transferring, lending, assembling, installing, maintaining, repairing, storing, trading out, disabling or disposing of radiation machines and their related components, or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State, shall be registered with the Department prior to performing such activities.

2.4.2.2 Each Service Company shall complete the Form R-60 series application for registration with all of the information required by the Department indicated on the form and all accompanying instructions, together with the fee required by Part 12, Category 22.

2.4.2.3 Each person applying for registration under 2.4.2 shall identify and provide:

(1) The service category for which registration is being requested, including but not limited to:

(a) Selling, leasing, transferring, lending, assembling, installing, maintaining, trading out, disabling or disposing of radiation machines and associated radiation machine components; and

(b) Servicing of radiation machines and associated radiation machine components, to include preventative maintenance, performance adjustment, calibration, or repair.

(2) The name and qualifications of each service technician who will provide service, including:

(a) Documentation of the training and experience that demonstrate compliance with the requirements of Appendix 2H; and

(b) Certification that each service technician has been instructed in, and demonstrates an understanding of the requirements of:

(i) these regulations; and

(ii) the Federal Performance Standard (21 CFR Chapter I, Subchapter J; and

(3) Documentation of the type of personnel dosimetric monitoring used that meets the requirements of 4.17 and 4.18; and

(4) A list of instruments that will be used to ensure that machine performance meets the manufacturer's specifications.

(5) Each servicing and services registrant under 2.4.2 shall notify the Department each time the registrant adds or deletes any service technician(s) to the list of service technicians authorized to provide radiation machine service(s).

(a) The registrant will be assessed ~~an~~ the acceptance review fee **required by Part 12, Category 24** when adding a technician, unless the technicians are added during a registration renewal.

**2.4.2.4 Service Company registration will be for a one (1) year period.**

**Comment [JJ23]:** Language is added for clarification to cross-reference the applicable Part 12 fee category.

**Comment [JJ24]:** Consistent with the proposed changes to Part 12 (fees for radiation control services), the Service Company registration process is changed from a biennial registration cycle to an annual registration.

81 2.4.3 Registration as a Qualified Expert.

82 2.4.3.1 Each individual who designs or evaluates protective shielding around a radiation area so  
83 the area meets the public exposure requirements of Part 4, shall be registered with the  
84 Department as a qualified expert designated QE(R), QE(S) or QE(T).

85 (1) Each individual who designs or evaluates shielding for a radiation machine regulated  
86 by Parts 8 or 9 and not used in the healing arts shall be registered with the  
87 department as a QE(S) and meet the requirements of Appendix 2C.

88 (2) Each individual who designs or evaluates shielding for a radiation machine used in  
89 the healing arts as regulated by Part 6, but not used in radiation therapy, shall be  
90 registered with the department as a QE(R) and meet the requirements of  
91 Appendix 2B

92 (3) Each individual who designs or evaluates shielding for a radiation machine used in  
93 radiation therapy as regulated by Part 24, shall be registered as a QE(T) and  
94 meet the requirements of Appendix 2B.

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96 2.4.3.2 Each Qualified Expert shall complete the applicable Form R-68 series application for  
97 registration and include all of the information required by the form and any accompanying  
98 instructions, together with the fee required by Part 12, Category 22.

99 **2.4.3.3 Qualified Expert registration shall be for a one (1) year period.**

**Comment [JJ25]:** Consistent with the proposed changes to Part 12 (fees for radiation control services), the Qualified Expert registration process is changed from a biennial registration cycle to an annual registration.

100 2.4.4 Registration as a Qualified Inspector.

101 2.4.4.1 Each individual who performs a certification evaluation of a radiation machine or an  
102 evaluation of a facility shall be registered with the Department as a qualified inspector  
103 who meets the criteria established in Appendix 2I.

104 2.4.4.2 Each individual who performs a certification evaluation on mammography, fluoroscopy or  
105 computed tomography machines used in the healing arts or, evaluates the quality  
106 assurance programs of digital imaging systems used in the healing arts shall be  
107 registered with the department as a qualified inspector with approval in the Registered  
108 Medical Physicist category.

109 (1) Individuals who perform a certification evaluation on Volumetric Dental Imaging  
110 Systems shall be registered with the department as a qualified inspector with approval in  
111 "Volumetric Dental Imaging Systems".

112 2.4.4.3 Each individual who performs registered medical physicist duties required by Part 24  
113 shall be registered with the department as a qualified inspector with approval in the  
114 radiation therapy Registered Medical Physicist category.

115 2.4.4.4 Each Qualified Inspector shall complete the applicable Form R-53 series application for  
116 registration and include all of the information required by the form and any accompanying  
117 instructions, together with the fee required by Part 12.

118 **2.4.4.5 Qualified Inspector registration shall be for a period of one (1) year.**

**Comment [JJ26]:** Consistent with the proposed changes to Part 12 (fees for radiation control services), the Qualified Inspector registration process is changed from a biennial registration cycle to an annual registration.

119 ~~2.4.4.5-6~~ Certification evaluation measurements shall be made with instruments that are  
120 sufficiently sensitive to determine compliance with these regulations.

121 (1) The instruments shall be maintained and used in good working order.

- (2) The instruments shall be calibrated at least every two (2) years, or in accordance with the manufacturer's recommendation, whichever is more frequent, or after any repair that could affect the calibration of the instrument.
- (3) Calibrations shall be NIST-traceable where such traceability is feasible.
- (4) Procedures for instrument calibration done by inter-comparison with a suitable and appropriately calibrated instrument must be approved by the department.
- (a) The comparison shall be between an instrument that has a current calibration traceable to NIST and an instrument for which a calibration factor is to be determined.
- (b) The comparison shall be made using the actual physical quantity to be routinely measured (for example, radiation energy/quality or visible light spectrum) and shall be compared in the same physical geometry.
- (c) The procedure(s) for inter-comparison shall be documented and available for review by the department.
- (5) In addition to the requirements in 2.4.4.65, instruments used for the certification evaluation report to measure the air kerma or air kerma rate of mammography machines shall be calibrated with an accuracy of  $\pm$  six (6) percent (95 percent confidence level) in the mammography energy range.

**Comment [JJ27]:** This section cross-reference is updated, consistent with the renumbering of (previous) section 2.4.4.5.

\* \* \*

2.6.3 For each radiation machine finding of noncompliance (Form R-59-1), the facility registrant shall:

- 2.6.3.1 Correct any failure of a radiation machine or imaging system to meet the requirements of these regulations or manufacturer's required specifications, within thirty (30) calendar days or as otherwise specified by the Department, in particular as identified on Form R 59 1, "X ray Machine Certification Evaluation Report."
- 2.6.3.2 Not use a radiation machine that has been determined to be unsafe for use, as determined by the criteria in Part 6, Appendix 6D, until subsequent certification by a Department-approved qualified inspector or the Department.
- 2.6.3.3 Permit only a person who has provided evidence of current registration with the Department in accordance with 2.4.2 to provide radiation machine servicing or services.
- 2.6.3.4 Notify the qualified inspector who issued the Certification Evaluation Report when the radiation machine violations have been corrected.
- (1) A copy of the Certification Evaluation Report, Form R-59-1, with the service repair certification signed and dated by the person providing service, shall be provided to the qualified inspector who initiated the certification evaluation..
- (2) A copy of any service report shall be provided to the qualified inspector upon request as evidence of completed corrective action.
- 2.6.3.5 Retain documentation that each indicated violation has been corrected to bring the machine into compliance in accordance with Section 2.6.6.
- 2.6.3.6 Pay the fee required by Part 12, **Category 25** for each certification label issued by the qualified inspector.

**Comment [JJ28]:** Reference to Part 12 fee category added for clarity.

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**PART 2, APPENDIX 2F: BONE DENSITOMETRY (BD) ADEQUATE RADIATION SAFETY TRAINING AND EXPERIENCE**

Each operator of a dual-energy x-ray absorptiometry system used on a living human shall meet the following education and experience requirements:

- 2F.1 Is certified or registered by:
  - 2F.1.1 ARRT(R), ARRT(M), ARRT(N), ARRT(T), or CNMT; or
  - 2F.1.2 The International Society for Clinical Densitometry (ISCD), combined with or including the didactic radiation safety training in 2F. ~~2A2.1~~, 2F. ~~2B-2.2~~ and 2F. ~~2C2.3~~; or

**Comment [JJ29]:** This change is unrelated to the proposed Part 12 changes, but rather to update cross reference errors consistent with the current numbering format for Appendix 2F.

\* \* \*